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Pharmaceutical Governance in Brazil: Globalization, Institutions and AIDS

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Pharmaceutical Governance in Brazil: Globalization, Institutions and AIDS

by

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Dedication

To my parents, Kathy and James Flynn, for their everlasting love and support throughout the years…

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Pharmaceutical Governance in Brazil:

Globalization, Institutions, and AIDS

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Abstract: The Acquired Immune Deficiency Syndrome (AIDS) caused by the human immunodeficiency virus (HIV) represents one of the greatest challenges facing today's globalized world. While state face increasing demands from their citizens to provide care and treatment, transnational drug companies have strengthened their market positions as a result of the Agreement on Trade-Related Aspects of Intellectual Property (or TRIPS). Patent protection provided by TRIPS has led to higher prices and reduced access to essential medicines, especially in low- and middle-income countries which are under increased pressure to provide expensive life-saving medicines to their citizens. Brazil's AIDS program is deemed successful in reducing morbidity and mortality rates through universal provision of free AIDS medicines. The program's sustainability came under threat as the result of TRIPS, pressures by transnational corporations, and trade threats by the US government. The research question that drove my dissertation centered on the impact of these threats on policy space available to Brazilian government to

sustain its universal social program. How has the incorporation of patent protections for drugs affected the ability of local firms to develop pharmaceutical technology and challenged states like Brazil to fulfill social democratic obligations? How has Brazil withstood challenges from transnational drug companies? In order to answer these questions, I employ mixed methods for gathering and analyzing data. These methods included ethnographic field techniques, content analysis, key informant interviews, and archival research. My findings are threefold. First, TRIPS has increased the power of foreign firms to secure monopoly positions in Brazil's drug markets and weakened Brazil's labs to quickly make generic copies of essential medicines. Second, policy space, though curtailed due to external pressures and treaty obligations, expanded through the development of symbolic power, or what I call "reputational dividends," based on a successful social program. Third, by adroitly marketing its banner AIDS program by employing human rights principles, health officials constructed a triple alliance between the state, local private drug manufacturers, and domestic activists tied into transnational advocacy networks. I employ institutional and power analyses to examine the changing sources of power for transnational capital, social movements, and state actors, as well as to analyze the impact patent protection has on the ability of Brazilian firms to produce medicines locally. I posit that globalization results in the formation of strong domestic coalitions who are capable of exploiting the "reputational dividends" of a successful social program in order to contest transnational corporate power. This symbolic form of power appears particularly well-disposed for "middle-income" countries that lack the material forms of power held by a global hegemon or transnational corporations.

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CHAPTER ONE – GLOBALIZATION, THE STATE, AND AIDS

AIDS requires a different logic.
AIDS has come to change the world
and has a pedagogical role.

-Rosali Tardelli, journalist and founder of AIDS News Agency [Agência de Notícias da Aids]

In 2001, at the first-ever Special Session of the United Nations General Assembly on HIV/AIDS, the leaders of 189 nations claimed that the epidemic Acquired Immune Deficiency Syndrome (AIDS) caused by the Human Inmmunodeficiency Virus (HIV) constitutes a "global emergency and one of the most formidable challenges to human life and dignity." In 2007, the Joint United Nations Agency on HIV/AIDS (UNAIDS 2008) estimates there were 33 million people who were living with the disease, 2.7 million new infections and 2 million AIDS-related deaths.

Of the total world population living with the disease, 95% are from the developing countries, which suffer chronic institutional weaknesses and lack of sufficient resources. Despite the large amounts of aid and support from international organizations, governments in the developing world are viewed as the main hope for an adequate response to the disease that involves prevention, treatment, and care (Barnett and Whiteside 2003a).

Most countries adhere to the notion that health care is a fundamental right for their citizens. At the time low and middle-income countries confront a crippling disease, they are called upon to fulfill human right commitments. The International Covenant on Economic, Social and Cultural Rights (United Nations 1966) asserts "the right of

everyone to the enjoyment of the highest attainable standard of physical and mental health." Many states are signatories of this agreement and have incorporated its principles into their constitutions.

The Committee on Economic, Social and Cultural Rights states that a core obligation to ensuring the right to health is providing access to biomedical innovations. Central to the provision of adequate health care for patients of HIV/AIDS is access to anti-retroviral treatments (ARVs), which has drastically reduced mortality and morbidity from the disease (United Nations High Commissioner on Human Rights 2001).

The extent and severity of the HIV/AIDS crisis has galvanized global responses, but unfortunately these attempts have fallen short of stated goals. The United Nations' "3-by-5" initiative had a target to provide three million HIV/AIDS patients with ARV treatment by 2005. However by the end of 2005, only 1.3 million people in low- and middle-income countries were receiving treatment—up from 400,000 in December 2003.

Achieving the goal of universal access depends on continued political commitment and available resources. Neither item is guaranteed for people living with HIV/AIDS (PLWHA) in developing countries. UNAIDS (2006:5-6) sums up the following dilemma:

> Prices of medicines have decreased dramatically, but cost still is an impediment in the context of per capita income and health expenditures, particularly but not exclusively in least developed countries. Prices of second-line antiretroviral are substantially higher than first-line, and not proportionate to local purchasing power; the prices of some HIV medicines in middle income countries remain higher than what would be expected in the context of per capita income.

Expensive drugs draw attention to the promise of globalization—the diffusion of technology comes at a price. There is no guarantee to access first-world products enshrined in the discourse of globalization.

In order to participate in the global economy and access the fruits of modern science, states are required to adhere to the Agreement on Trade-Related Intellectual Property Rights (TRIPS), one of the pillars of the World Trade Organization (WTO). The accord universalizes a vision of how innovations are produced, distributed and compensated, as well as stipulates the rights and obligations between inventors and consumers. While states must provide minimum standards for protecting intellectual property, such as a twenty-year period for patents, TRIPS and subsequent declarations provide a number of flexibilities governments may employ to incentivize industry and protect their citizens.

The case of Brazil encompasses the conflicting demands due to AIDS and globalization. In fighting the epidemic, South American's largest country has stood out in its commitment to providing free, universal access to treatment. Its Constitution recognizes the right to health care based on principals of universal access and equity for its population of 200 million. To guarantee access to affordable medicines for HIV/AIDS patients, Brazil has decided to invest in local production of medicines by public (or state-owned) labs and has confronted transnational corporations (TNCs) that market patented ARVs. These initiatives, however, are structured by Brazil's obligations to respect intellectual property and work within the global division of labor in pharmaceutical production.

Brazil's AIDS program is unique, not only for low- and middle-income countries, but also compared to the rest of the Brazilian health system, which suffers from lack of resources. Due to the First World standards of care and the treatment Brazil's program offers, it is worthy of study in light of globalization. In so far as the TRIPS accord and rhetoric concerning openness to global flows of technology, capital, and information presuppose improving the quality of life, Brazil's program reveals the challenges that

other countries will face in ratcheting up their AIDS or other health care programs to First World levels of care.

Theoretically, the case of Brazil allows us to explore some of the postulations related to globalization and state autonomy. Political leadership and civil society mobilization have remained constant throughout the development and execution of AIDS policies. But the inclusion of patents on medicines allows us to examine the before and after effects of new global institutional structures and the impact they have on local production of essential medicines and a cash-strapped public health system. Brazil's experiences in walking a fine line between globalizing pressures and national rights-demands are summed up in the following research questions:

1. What is the impact that intellectual property laws on pharmaceuticals, enshrined in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), have had on Brazil's ability to respond to national crises, develop local capabilities, and challenge the interests of the transnational drug companies?

2. How was Brazil able to confront transnational drug companies to ensure the sustainability of its treatment program, and how has Brazilian state society collaboration in addressing the AIDS epidemic affected state autonomy when confronting transnational companies?

The dissertation seeks to understand how actors respond to new structural forms of power wrought by globalization. Instead of re-working macro-sociological theories of change, I use a variety of conceptual tools drawn from different schools of social theory. By doing so, I avoid the problem of endogeneity; that is, studying a subject matter such

as transnational corporations or states in their own terms. Instead, I construct a relational sociology that focuses on the material and symbolic interactions between states, transnational corporations, and social movements.

Theoretically, my dissertation draws from three dominant schools of thought. First, I employ concepts from neo-Weberian perspectives that conceptualize the state as an actor capable of developing its interests beyond the particularitistic interest of groups from society. State autonomy, however, remains contingent on its internal organization and forms of embeddedness to other groups of society. Next, I employ the concepts of mobilizing structures, political opportunities, framing and identities from social movement literature to explain how forms of embeddedness change over time. The mediating links between society and state are constructed by "social movement insiders" (Santoro and McGuire 1997) under a rubric of citizenship and human rights. Lastly, analyzing the subject of the AIDS epidemic requires the concepts of stigma and exceptionalism that are so intertwined with the disease. Stigma helps us understand the internal coherence and transnational outreach of those affected by the disease, while exceptionalism draws our attention to the international and national forms of state-building to address the pandemic.

I employ institutional and power analyses to examine the changing sources of power for transnational capital, social movements, and state actors to analyze the impact patent protection has on the ability of Brazilian firms to produce medicines locally. I posit that globalization results in the formation of strong domestic coalitions who are capable of exploiting the "reputational dividends" of a successful social program in order to contest transnational corporate power. This symbolic form of power appears particularly well-disposed for "middle-income" countries that lack the material forms of power held by a global hegemon or transnational corporations.

My account draws from the comprehensive studies carried out by Amy Nunn (2007) and João Biehl (2007). Nunn shows how treatment policies became institutionalized across several different government administrations. Political leaders who questioned the program saw their political career cut short while other politicians were able to make political gains by expanding the program. Biehl emphasizes the role of an "activist state" in taking a pro-active role to combat the disease, initiating partnerships with NGOs for carrying out prevention and care projects, and organizing government efforts in response to congressional and presidential mandates. My work delves deeper into the pressures of transnational drug companies, industrial policies, and activism around intellectual property. I enter the black box of pharmaceutical value chains and the roles market power and patent power play in the pendulum between autonomy and dependency.

CASE STUDY SELECTION

Middle Income Countries with AIDS Crises

Why was Brazil able to scale up its AIDS program to the global level? The South American country is not unlike other middle-income countries with comparable initial conditions. Thailand, South Africa, and India also suffer AIDS epidemics and enjoy a strong pharmaceutical base. All these countries face comparable global forces, pressuring them to conform to an international intellectual rights regime and compete in the global knowledge-based economy. Besides India's established democratic tradition, all the countries have witnessed recent transitions to democracy driven by social movements fighting for citizenship rights. (Thailand, however, has experienced continued military

intervention in its politics.) And all these countries have become flashpoints in the struggle between transnational drug companies and the state.

Table 1 provides a brief comparison of these four countries' indicators in terms of wealth, poverty, inequality, the AIDS epidemic, and government effectiveness. Brazil's GDP per capita is comparable to South Africa and Thailand, while India, the country with the largest population, trails in per capita income. In terms of social indicators, Brazil lies towards the higher end of inequality, as measured by the Gini coefficient. Brazil's poverty levels are comparable to India and between the extremes of South Africa's extreme inequality and Thailand's low poverty rates.

Table 1: Four Middle-Income Countries with Serious HIV/AIDS Epidemics[1]

	Brazil	South Africa	Thailand	India
Population (millions in 2008 est.)	196	48.8	65.5	1,148
GDP (2007 est. in billions by PPP)	$1,849	$468	$522	$2,966
GDP per capita (2007 est. PPP)	$9,500	$9,700	$8,000	$2,700
Inequality (Gini)	56.7 (2005)	65 (2005)	42 (2002)	36.8 (2004)
Population below poverty line (est.)	31% (2005)	50% (2000)	10% (2004)	25% (2007)
HIV/AIDS adult prevalence rate (2003 est.)	0.7%	21.5 %	1.5%	0.9% (2001 est.)
People Living with HIV/AIDS(2007 est.)*	730,000	5.7 million	610,000	2.4 million
% of PLWHA with access to ARVs (2007 est.)*	80%	28%	61%	(7%)***
Year Recognized Product Patents	1997	1978	1992	2005
Government effectiveness (percentile rank 0-100)**	55.0	75.6	66.0	54.0

Sources: CIA Factbook (2008); *UNAIDS (2008); and **Kaufmann, Daniel, Aart Kraay, and Massimo Mastruzzi (2006). ***Estimates being updated.

Every country faces an AIDS epidemic, but South Africa's situation has reached genocidal proportions with close to one-in-five adults affected by the disease. South Africa and India are comparable given the slow state response to the disease, despite capable governments and a strong pharmaceutical sector. India, due in part from its late adherence to TRIPS, now has one of the strongest generic pharmaceutical industries in the world, but it has been slow to roll out treatments to its own population.

[1] All monetary values are in US dollars unless specified otherwise.

Thailand has followed Brazil's path in aggressively rolling-out ARV treatment, and faces similar challenges in producing medicines locally due to changes in its patent law that allow for protection of product patents in 1992. Thailand also has a public lab, the Governmental Pharmaceutical Organization, which is comparable to Brazil's federal drug maker, the Medicines and Drugs Technology Institute (Instituto de Tecnologia em Fármacos—Farmanguinhos). Both state-owned companies specialize in drug formulations, and their managers lobby for compulsory licenses to produce patent-protected medicines. Despite their similar approaches to dealing with AIDS, Brazil and Thailand have distinct political cultures and experience in institutional building.

In terms of government effectiveness, (understood as the quality of public service provision, quality of bureaucracy and civil servants, and the independence of the civil service from political pressures), there appears to be no connection in this small sample between government effectiveness and the number of People Living with HIV/AIDS (PLWHA) receiving treatment (Kaufmann et al. 2006). But ratings on government effectiveness take a holistic view of government structures, whereas individual state organizations may prove to be exceptions. In this respect, Brazil, more than any other country in Table 1, has exhibited the most dedicated and extensive state action to combat AIDS.

Understanding Brazil's Uniqueness

Brazil's AIDS policies in general and treatment program in particular is acknowledged as one of the best, if not the best, in the developing world (Hass 2003; Cruz, Kowalski, and McPake 2004). In fact, contrary to the belief of most experts at the

time, Brazil demonstrated that it was possible for a developing country to implement a treatment program comparable to First World standards. This fact rules out diffusion and increases the purity of the Brazilian case. The success of the Brazilian AIDS model has resulted in numerous studies and an extensive bibliography. While these materials are used as sources and checks on validity, my contribution is to analyze the changes in the internal reorganization of the state and varied forms of social embeddedness in the context of globalization.

A response as to why Brazil provided universal treatment to its citizen who had contracted AIDS and confronted the United States and transnational drug companies is quietly simply because it could. Indeed, Brazil enjoys a pharmaceutical base and was able to mobilize public (or state-sector) pharmaceutical laboratories for the public health crisis (Flynn 2008). In total, these public labs are capable of producing over 10 billion pharmaceutical units/year in 195 formulations using 107 active ingredients (Egléubia Andrade de Oliveira, Maria Eliana Labra, and Bermudez 2006).

Furthermore, Brazil is a rising economic power (Flynn 2007; Brainard 2009) and has a significant consumer market. For example, 37 million people own private health insurance. But the country's pharmaceutical sector, like many other aspects of its economy, remains dependent on imported technology and finance capital. Given the size of its middle class, why did the country institute a universal treatment policy as opposed to means-tested programs implemented in other countries, including the US?

Much of the literature on the Brazilian case highlights a certain aspect of the policymaking process and/or purports an essentialist argument about the country's uniqueness. Policy makers, be they politicians or civil servants, emphasize their role and perspective in the development of Brazil's AIDS policies. Fernando Henrique Cardoso, who was Brazil's president from 1995 to 2002, declared that his aim was to make

government more transparent and increase partnerships between state and society when many of the policies were enacted. In the case of AIDS, this reached its maximum potential so much so that "state and the social movement practically fused" (Biehl 2004: 115).

Jose Serra (2004), who was Minister of Health under Cardoso and attempted succeed him, also emphasizes the important partnerships with civil society in AIDS programs. In his view, if politicians and policy makers had known ahead of time the challenges and difficulties, they probably would have shied away from the extensive efforts that were required when facing down pressure from the United States and powerful pharmaceutical companies. These declarations from the top levels of power reveal how democratic change resulted in increased attention by politicians on citizens' demands. Their actions seem rational, but their reflections sidestep the question of why government leadership and commitment occurred in AIDS as opposed to other rights claims from mobilized constituencies such as in the areas of land reform or racism.

Another reason given for Brazil's uniqueness is the historical legacies of strong central government action in fighting threats to public health especially when compared to other countries (Gauri and Lieberman 2006; Gomez 2006). Brazilian public health authorities have a more collective approach to infectious disease as a national problem and have developed strong autonomous health agencies.

Guari and Lieberman (2006) argue that in South Africa, strong boundaries between social groups have reinforced distinct racial identities that resulted in increased stigma, on the one hand, and reduced perceptions of the risk of contagion across racial boundaries, on the other. For one, Brazilian social boundaries in which racial identities are dismissed tend to be more fluid. Since neither an identifiable group can be blamed for spreading the disease nor are members of a group forced into denying responsibility for

the epidemic on behalf of their collective identity as in the case of South Africa, Brazilian perceptions of collective risk and susceptibility are more encompassing. Consequently, Brazilian policy makers were able to define AIDS as a collective problem for which they were able to develop a unique and successful program of prevention and treatment.

Brazil's does have a capable public health complex, especially compared to other developing countries. Historically, health policies have been based on a corporatist model where benefits have been tied to formal employment. Important changes occurred during the 1990s after the country returned to democracy (detailed in Chapter Two). Despite recent efforts to provide universal access to care, Brazil's public health system continues to face problems of adequate financial resources and reforms to ensure equity across social classes. AIDS, however, has received special attention compared to other (perhaps more problematic) infectious diseases like tuberculosis and dengue fever.[2]

Brazilian policy makers and scholars also highlight the country's open sexual attitudes as reasons for its successful program. The country's carnival celebrations are world renowned. Compared to Russian conservative attitudes towards sexuality and homosexuality, Brazil has never embraced dark Victorian taboos against open expressions of one's sexual orientation (Gomez 2006). Such a depiction veers toward an essentialist view of Brazilian sexuality. Brazilian promiscuity could be seen as the myth of the sexual prowess of African males applied to an entire country, but in fact, Brazil's initial policies towards the disease were warped by denial and blame. Only ten years after the first diagnosis of AIDS did the country ramp up efforts to fight it.

Lastly, scholars and policy makers also explain the importance of Brazilian civil society in the program's evolution and success. Many of the depictions, however, tend to

[2] See Rich and Gomez (2009) for a comparison of policies addresses AIDS versus tuberculosis.

fetishize the role of social movements. "The rich social movement responding to AIDS in Brazil from 1985 to 1995 cannot be understood without reference to the international movement and to the historical moment lived then by Brazilian society, which was overcoming two decades of military rule" (Cristiana Bastos 1999: 149). Parker (1997, 2003), similar to Bastos, describes how non-governmental organizations (NGOs) were organized not as part of a gay movement such as in the US but as part of human rights movements that sprouted in the transition to democracy.

Throughout most of Latin America, the norm is for government to outsource its responsibilities and duties to NGOs (Roberts 2005). But in the case of AIDS in Brazil, this relationship evolved differently. One important distinction is the middle class AIDS activists who know their rights and were able to press their claims against the state (Rich 2009; Serra 2004). The middle class origins of those affected by the disease are important, especially when compared to the spread of the epidemic in South Africa where it has spread rapidly through a racially distinct and disadvantaged underclass. Brazil's activists groups painstakingly undertook court actions to guarantee government protection against discrimination and secure care and treatment from the state (Passarelli and Júnior 2003).

There are many elements that contributed to the success of Brazil's program. Any factors highlighted in the aforementioned accounts leads to reductionism (and many of these scholars do highlight more than one important factor). My own description of the construction of Brazilian pharmaceutical citizenship in Chapter Two emphasizes some of these factors, but does not attempt to make a conclusive statement or add much new material.[3] This review, nonetheless, touches about a number of theoretical debates and

[3] In fact, Brazil's success has important limitations due to historical inequalities and structural marginality (Biehl 2007). Perhaps the construction of Brazil's success is more the result of strategic marketing than concrete reality.

concepts in sociology concerning globalization, state autonomy, social movements, and AIDS, which will explain Brazil's success.

THEORETICAL FOUNDATIONS

Debates about State Autonomy

Explaining Brazil's uniqueness and ability to confront transnational capital begs the sociological imagination to unravel the mysteries of state power. The history of the country's economic and institutional development, like much of the rest of the developing world, has been contingent on its relations to the larger world system (Wallerstein 1974; Cardoso 1972). Its experience with capitalist development has resulted in a high degree of structural inequality, but at certain times, especially the decades during and after World War II, state elites have pursued a national development project that appears to transcend class boundaries.

Brazil's institutional development provides fodder for classic sociological debates about the nature of state. The point of departure in Marxist thought is the idea that the state is merely the "executive committee of the bourgeoisie" (Marx and Engels 2002). Apart from Bonapartist formulations in which a dictatorial figure assumes control, scholars from this perspective have developed structuralist and instrumentalist versions of Marx's original formulation. The structuralist version argues that the state operates in the long term political interests of capitalists (Poulantzas 1976), while the instrumentalist account views state action as driven by an elite who share the same values, interests, and

background of capitalists and for this reason tend to develop institutions and policies in their favor (Miliband 1969).

Theoretical attempts at synthesizing the two views argue that structural components have developed to support long-term capitalist accumulation, but the construction of new institutions in the governing apparatus favors instrumentalist accounts, albeit based on class struggle, so that the structuralist bias towards capitalist interests is not a foregone conclusion (Block 1977).

The Weberian perspective of the modern bureaucratic state argues that it is not necessarily reducible to class analysis. Rather, the state is a potentially autonomous actor in society based on its central rule-making ability over a geographically defined area. Once created, bureaucratic states develop their own rationality, which tends to be more instrumental and universal than the varied rationalities and interests found in society (Weber 1946). The state can be defined as a conglomeration of bureaucratic agencies and institutional structures "charged with administrating policies, maintaining order, enforcing the law, securing political legitimacy, and collecting the revenues necessary for the functioning of the state apparatus and the implementation of state polices" (Itzigsohn 2000: 13).

From this Weberian perspective, Mann (1986) argues the state is ultimately an "arena" and it is from this fact that it derives its autonomy. The four elements of state power include a set of differentiated institutions whose power emanates from its centrality over a territorially demarcated area. The monopoly of "authoritative binding rule-making" is backed by its monopoly on the legitimate use of force. Given the space it occupies in modern society and the multiplicity of functions that affect different interest groups, states can gain autonomy by practicing a "divide and rule" strategy (Mann 1986).

The state's power, nonetheless, remains tied to its interplay with other social forces in society.

The idea of state autonomy has played an important role in the study of Third World countries. This approach matured during the 1980s and 1990s with various forms of comparative institutional analysis (Evans, Rueschemeyer, and Skocpol 1985). The underlying assumption is that, since state structures develop variably through time and differently across countries, we can expect to observe different social and economic outcomes. The economy is embedded in state institutions just as uneven development conditions the growth of the state (Polanyi 1944; Block and Evans 2005). In development studies, especially those seeking to understand the economic development of Japan and other fast-growing East Asian countries, scholars argue that an autonomous developmental state could rise above particularistic interests and effectively govern the market (Wade 1990; Amsden 2001).

The concept of embedded autonomy, developed by Evans (1995), seeks to understand the varied institutionalized channels of state and societal relations by uncovering the social bases of a successful developmental state. Embedded autonomy derives from the internal organization of state agencies and the forms of social ties between civil servants and civil society actors. Where bureaucrats have clear career paths and strong forms of solidarity, states have the potential for becoming autonomous and work towards a self-defined national interest. But just as important, Evans asserts, are the formal and informal institutionalized channels between bureaucrats and society in order to exchange information about each others' capabilities. The concept of embedded autonomy represents a refinement of Evan's idea of the "triple alliance" (Evans 1979). The latter concept, derived from dependency analysis, conceives of the state as mere arbiter of the relations between TNCs and the local bourgeoisie.

The neo-Weberian view of state autonomy formulated by Evans and others is challenged by scholars of globalization. Marxists inspired by the instrumentalist version of the state argue that the social ties binding the state to society have become global in nature, and that these networks are stronger between policy makers and executives of transnational corporations than between state elites and their citizens (Sklair 2001; Robinson 2004). Globalization, especially with the rise of global capitalist institutions like the World Trade Organization, has reduced the autonomy of the developmental state to enact policies that have been successful in the past (Wade 2003). This perspective emphasizes that globalization has increased dependency.

Neo-institutionalists come to a similar but more nuanced version of state autonomy in the age of globalization (Meyer, Boli, and Thomas 1997). As a result of increasing emulation and transmission of institutional models across national boundaries, they argue that globalization has resulted in a state that is stronger organizationally, but at the same time more disciplined and tame. The state's infrastructural capacity to act has increased, but so have global norms and pressures that inhibit independent action (Meyer et al. 1997).

Theories of globalization and state-centric perspectives from the neo-institutional schools suffer from the problem of studying a social phenomena within its own terms, often times, at a macro-level. Sassen (2006: 4) correctly identifies the problem with most theories of globalization as suffering from the "endogeneity trap": "we cannot understand the x—in this case globalization—by confining our study to the characteristics of the x—i.e., global processes and institutions." In other words, analyzing globalization as new telecommunication technologies, growing interdependence, establishment of global institutions, the decline of the national state, and increasing

power of transnational corporations (TNCs) to override borders and national governments amounts to a description of globalization—not an explanation.

The same criticism of endogeniety can be laid out against state centric accounts that allege nothing has changed as a result of global processes, or that globalization merely places new constraints on policymaking without explaining their nature, impact, and outcome of these policy constraints. At one extreme, Campbell (2004) argues that globalization has had a minimal impact on national institutions. His view downgrades the alleged impact of new global institutions such as the WTO and the increasing power of international capital on domestic economies. The problem becomes acute when analyzing the forces behind the ability of states to protect social rights.

Globalization is perceived as affecting the ability of developing countries to pursue social-democratic goals. Studies on social expenditures in developing countries confirm globalization's negative impact on the ability of these countries to maintain safety nets (Rudra 2002), but this is not a foregone conclusion. As a close study of the success of social democracy in the global periphery argues, "both state capacity and grass-roots pressures become essential for preserving social conquests: the former as the locus of strategic innovation and planning, and the latter as a constant political counterbalance to the pressures of globalization" (Sandbrook 2007:226). Historical institutionalists adopt a similar argument.[4] But what are the mechanisms involved to counterbalance globalizing pressures and norms?

[4] Skocpol, for example, explains the inertia of successful state actions in the following terms: "a policy is 'successful' if it enhances the kinds of state capacities that can promote its future development, and especially if it stimulates groups and political alliances to defend the policy's continuation and expansion" (Skocpol 1992: 59). The 'lock-in' mechanism, in the case of successful AIDS policies, is the effective roll-out of treatment to all those requiring medicines. It is not just the *de jure* or legal mandate to provide medicines; it is also the *de facto* achievement that transforms the fulfillment of a social right into a powerful mobilizing force.

While many states in the developing world – especially middle-income countries – enjoy a degree of infrastructural capacity, the development of stronger ties between their elites and global corporate elites as a result of global capitalism is not a foregone conclusion. Instead, strong ties may develop between civil servants and local "grass-roots" organizations and/or transnational advocacy networks. How state-society ties are based more on conceptions of citizenship and social rights in the latter case, as opposed to corporate material interests in the former, becomes a theoretical and empirical question.

States and Social Movements

Brazil is a hotbed of social movements. In fact, it is home to one of the largest social movements in the world—the Landless Workers' Movement (Movimento dos Trabalhadores Sem Terra). But no other social movement in Brazil has achieved the same success in institutionalizing citizenship claims domestically, nor had to scale up its struggle to the global level to maintain its achievements, than Brazil's grassroots mobilization around AIDS.

Just as in the case of sociological debates about the state, Brazil provides useful fodder for competing theoretical ideas about social movements. In the first camp are structuralist accounts of contenders versus state elites, while a second culturalist perspective concerning the rise of new social movements emphasizes post-industrial concerns, subaltern identities, and emotional underpinnings. Scholars of the first school are political process theorists and argue that social movements include rational planning and balance of power calculations. The main concepts of the political process model used

to understand the "dynamics of contention" are mobilizing structures, political opportunities and framing (McAdam, Tarrow, and Tilly 2001; McAdam, McCarthy, and Zald 1996).

The concept of mobilizing structures comes from resource mobilization theory. The framework, criticizing previous accounts of social movements as irrational forms of collective behavior resulting from relative deprivation or strain, argues that sustained collective action requires organizational structures and a constant stream of resources in terms of labor, people, and money (McCarthy and Zald 1977). Mobilizing structures are defined as "those collective vehicles, informal as well as formal, through which people mobilize and engage in collective action" (McAdam 1996: 3). The use of mobilizing structures in this dissertation looks beyond the actions of social movement outsiders and considers the interactions of social movement organizations with state actors.

Political opportunities are the set of political constraints and opportunities unique to a particular context and are embedded in the broader processes of society (McAdam et al. 1996). They involve shifts of power in democracies, as well as the openness of strong and weak states to societal forces. The concept draws attention to the elite reactions and splits that result from pressures arrising below (McAdam 1982, 1996). The mobilization of resources does not happen in a political vacuum. Rather, the rise and fall of social movements is related to political objectives. Confrontations between TNCs and state elites, for example, reveal the breakdown of global consensus about the legitimacy of patent monopolies.

In the political process model, framing processes are "conscious strategic efforts by groups of people to fashion shared understandings of the world and of themselves that legitimate and motivate collective action" (McAdam et al. 1996: 6). Framing processes seek to undermine an institutional structure's legitimacy and encourage mobilization as

people seek to organize and act on growing awareness of a system's vulnerability, such as global patent regime. Collective action frames "underscore and embellish the seriousness and injustice of a social condition or redefine as unjust or immoral what was previously seen as unfortunate but perhaps tolerable (Snow and Benford 1988: 137).

Political process theory employs the concept of framing in a rational, calculative manner. However, the term provides a useful bridge to the other culturalist perspectives that seek to explain the rise of new social movements concerned with identity and dominant values of a system (Jasper 1997; Melluci 1996). This school argues that social movements cannot be reduced to accounts based on rational-choice theory or to structuralist perspectives of the state. This perspective underscores the importance of solidarity based around a common identity, such as a sexual orientation or a stigmatizing disease.

The two paradigms of social movement theory—political process model and the new social movement theory—require theoretical adjustments when applied to developing countries in a globalizing world. Davis (1999), for example, argues that neither perspective applies to the Latin American experience; instead, the uneven development of the state must take center stage. Indeed, scholars of social movements in wealthy countries argue that underprofessionalized state bureaucracies will discourage challengers, while "[c]oherent state bureaucracies with social policy missions will encourage challengers targeting those issues," (Amenta and Young 1999: 161). Consequently, we should see stronger social movements in countries with stronger resource capabilities and probably weaker or more violent movements in poorer, undeveloped states.

A criticism specific to the political process model is that scholars have focused more on explaining the rise in social movements than in accounting for successful

outcomes. This becomes even more problematic when applied to developing countries, many of which are new to democratic politics and have varied degrees of institutional development. Democratic openings allow for new political possibilities for rights claims to be translated into reality (Jelin 1996), while the substantial fulfillment of rights obligations by states only results from increasing managerial improvements in public administration (Roberts 2005). The question then revolves around the nature of the social ties across the state-society divide and how they feed into mobilizing structures.

There are both apolitical and politicized ties that can bind civil servants and grassroots organizations. Evans' (1996) concept of synergy identifies the importance of complimentary state structures and society organizations as well as their embeddedness for the development of trust. Another view emphasizes the politicized nature of these alliances that lead to alternative paths of development (Hickey and Mohan 2005). The former foresees the gradual diffusion of development successes where we find high levels of social capital are found, whereas the latter underscores the social struggles that result in novel progressive achievements.

Brazil's AIDS program is the consequence of a politicized base in alliance with committed public health activists who have achieved managerial roles in the state bureaucracy. The concept of "social movement insiders" (Santoro and McGuire 1997) used in this dissertation refers to the professional managers in the state who are activists themselves are interested in achieving social movement goals. The concept allows us to view the state in an instrumentalist fashion not necessarily working at the behest of capitalist interests, but open to capture by social movement forces. Under the rubric of human rights, these institutional insiders play key roles in funneling information and resources to social movement organizations on the outside, especially during political opportunities that result from confrontations with TNCs.

Globalization provides another dynamic to the nature of state-society ties. Many of today's sustained collective actions are organized into transnational advocacy networks and not reducible to groups located in a national state (Tarrow 2005; Keck and Sikkink 1998). These organizations coalesce around a transnational symbolic code of human rights embodied by declarations made by international government organizations.[5] The global diffusion of human rights does not occur apolitically by experts providing rational models for emulation according to world polity paradigm; rather, the process remains highly political (Keck and Sikkink 1998).

Unlike the "boomerang" model of Keck and Sikkink (1998), whereby activists in developing countries seek support of transnational networks to put pressure on their own countries, this analysis of Brazil reveals coalitions from middle income countries reaching out to transnational networks to mobilize support against corporate-led globalization. Through "frame extension" facilitated by global communication circuits, activists are able to connect "two or more ideologically congruent but structurally unconnected frames regarding a particular issue or problem" (Snow and Benford 1988).

The "human rights frame" provides the backdrop for several diverse groups and actors, such as gay rights groups, the access to medicines movement, and consumer advocacy groups, to coalesce into a large movement that can defend social rights states and blame corporate-led globalization for social injustice. The frame is even more empowering when backed by the visible success of a social program. The concept "reputational dividends" developed throughout this dissertation draws attention to social mobilization in defense of a program based on human rights principles.

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[5] The United Nations Development Program (2003), for example, explains that "in a human rights-based approach to development, human rights determine the relationship between individuals and groups with valid claims (rights-holders) and State and non-state actors with correlative obligations (dutybearers). It works towards strengthening the capacities of rights-holders to make their claims, and of dutybearers to meet their obligations."

AIDS and Social Theory

AIDS is a relatively new disease. Social scientific research into understanding the virus' effect on society has a short but prolific history. There is no comprehensive theory about AIDS and society; however, there are important social characteristics about the disease. The two most important concepts are stigma and exceptionalism.

Stigma is the social definition of individuals and groups who possess undesirable traits or attributes and, in the extreme, involves classifications of certain social groups as dangerous and harmful to the rest of society (Goffman 1986). The ways in which AIDS is transmitted, the cultural definitions of immoral behavior, and the deadly consequences of infection (at least initially) combine to increase the stigma of identifiable groups and vitiate public efforts to cope with the disease (Deacon et al. 2005). Stigma attached to AIDS is compounded by the fact that public awareness of the virus occurred with its spread amongst the gay male community in the United States (Shilts and Greider 1987).

Gay communities in the United States and Europe spearheaded efforts–along with other stigmatized groups such as intravenous drug users, Haitian immigrants, and hemophiliacs–to change public perception of AIDS and pressure governments to initiate public policies addressing issues of discrimination and access to health care. The stigma attached to the disease combined with the identity politics of the gay rights movement created the conditions for powerful collective mobilization and empowerment towards social change (Parker and Aggleton 2003). Depending on social structures, sexual mores, and public institutions, the development of collective action around AIDS varies in different social contexts, but apart from issues of outright denial by government officials,

public policy towards AIDS has been marked by a high degree of exceptionalism. The concept of exceptionalism, originally specified by Bayer (1991), is used in this text to refer to the willingness of public officials to try innovative approaches and disburse large amounts of money to fight the disease (Rosenbrock et al. 2000).

The exceptionalism of AIDS as a disease becomes even more apparent when we move from the national to the global scale. The pandemic highlights the social contradictions inherent in the contested concept of globalization (Altman 1999). The increase of cross border mobility and instantaneous communication provides the social spaces for mutual accusations of blame and neglect as well as the possibility for globally coordinated efforts. Indeed, AIDS is the first disease that has been classified by the United Nations Security Council as a threat to human security. No other public health concern has been able to mobilize such substantial resources from the global community. The degree of AIDS exceptionalism is apparent in UN declarations, the establishment of a specific UN body to coordinate international efforts, and creation of dedicated funding bodies to direct resources to fight the disease.

The compression of space-time associated with the globalization also encourages the rapid dissemination of successful (or unsuccessful) institutional models in the fight against the pandemic and facilitates actions by transnational advocacy movements, either through the identity politics of affected groups affected or human rights organizations supporting their cause. While HIV/AIDS is global in nature, national governments remain the primary institutional actor for implementing comprehensive programs to combat it (Barnett and Whiteside 2003b). Countries that fail to develop adequate policies and programs become the target of global public condemnation, while successful programs garner global praise and become models for others to adapt. States, furthermore, can reap what we can here call reputational dividends of a successful social

program when confronting global capitalist pressures. When doing so, states can increase their ability for autonomous action, both at the national and international arena.

DATA COLLECTION AND ORGANIZATION

Data collection for my dissertation included policy documents, news reports, descriptive statistics and ethnographic techniques. Policy documents came from online resources provided by the Ministry of Health and related government agencies, as well as any documents not available online but delivered directly by government agencies. Government documents also involved archival research of US diplomatic cables concerning Brazil's use of compulsory licenses that were obtained through requests under the Freedom of Information Act (FOIA). News reports came from leading Brazilian business press such as Valor Econômico, online websites specializing in reporting access to medicines Boletin Farmacos, as well as government agencies that regularly report issues such as Brazil's National AIDS Programme website.

Quantitative data included the evolution of drug prices, government budgets, and the number of patients on ARVs. Secondary statistics were obtained from the Ministry of Health, especially the National AIDS Program website, and additional sources of quantitative data include other government agencies involved in industrial policies as well as industry associations that collect market information.

Key Informant Interviews

Ethnography was the main research technique to acquire new empirical material in the natural social setting (Fielding 2001). The key ethnographic techniques were semi-structured and open-ended interviews, observations of industry conferences and AIDS congresses, and visits to pharmaceutical production facilities. Visiting production sites provided an opportunity to learn about the intricacies and challenges of the drug-making process. Observing meetings about the development of the local drug industry and conferences about AIDS policies provided me with the opportunity to make new contacts, witness who gathered to share information, and note the value-orientations of their social interactions. Specifically, employing ethnographic techniques allowed me to observe and interrogate the ideological conflicts between defenders of strong forms of intellectual property and human rights activists.

Key informant interviews were the main vehicle for obtaining in-depth knowledge of Brazil's policy-making process and understanding the social ties across the state-society interface. Sampling was not random but directed towards those individuals who have played a role in lobbying, formulating, and implementing pharmaceutical policies or who have been directly affected by the policies, such as industry and patient groups, as well as those who have insider knowledge concerning the process, such as policy and industry experts. Sampling strategies included the following:

1. Convenience Sampling: This sampling strategy involves engaging my social network to establish contact with target interviewees. Concerning access issues during my pre-dissertation research June-August 2005, I developed an extensive network of contacts in government, non-governmental, and policy experts during my pre-dissertation research June-August 2005. Through this initial period, I was able to gain institutional support at the Center for Pharmaceutical Policies

(Núcleo de Assistência Farmacêutica—NAF), which is part of the Sergio Arouca National School of Public Health (Escola Nacional de Saúde Pública Sergio Arouca—ENSP) and provided additional contacts.

2. Snowball Sampling: The use of snowballing techniques was my main strategy to gain access to restricted groups. For example, I sampled executives by first contacting industry associations that represent these groups.

3. Quota Sampling: Interviews with individuals who have participated or directly witnessed the evolution of Brazil's pharmaceutical sector over the past twenty years were especially helpful. These sub-groupings included representatives from advocacy organizations, policy makers at the National AIDS Program and Ministry of Health, managers from transnational drug companies, public (state-owned) labs, and private Brazilian drug companies as well as specialists from law, academia, and journalism.

I was flexible in the sampling so that I could include any individuals for interviews based on snowballing techniques. Interviewing began in October 2007 and concluded in September 2008 while I was in the field. Interviews also included pre-research and follow-up interviews. Appendix Two lists all the interviews, conferences attended, and manufacturing facilities visited[6]. In total, I interviewed 60 people. I conducted most of the interviews in Portuguese by digitally recording and translated them into English. I was not able to interview everyone I desired. Some executives at

[6] In some cases, interviewees spoke off the record. When this occurred, no personal identifiers were associated with them.

transnational pharmaceutical companies and some current and past high-level policy makers at the Ministry of Health denied my interview requests out of lack of interest, busy schedules, or perhaps out of fear.

One obstacle I encountered while in the field was that I had to discontinue my interviews until I received the approval of the Ethic Committee in Research (Comitê de Ética em Pesquisa—CEP) at the National School of Public Health, which provided me with institutional affiliation. I had received approval from the Institutional Review Board (IRB) at the University of Texas at Austin before entering the field. I only encountered difficulties with Brazil's version of the IRB when attempting to make contacts and set up interviews with high level policy makers at the Ministry of Health. I had to stop the interviews for three months to complete the bureaucratic process.[7]

While institutional support from the National School of Public Health presented certain obstacles with research ethics committees, its Center for Pharmaceutical Policies (Núcleo de Assistência Farmacêutica—NAF) provided other forms of invaluable support. NAF colleagues (or Nafinhos) had accumulated extensive knowledge of Brazil's health system and pharmaceutical realities that they liberally shared with me. As mentioned above, Nafinhos had an extensive network of contacts in government, civil society, and industry. At various conferences and events, some would introduce me jokingly as a researcher from the US' Central Intelligence Agency, but "of the good kind." This naturally leads to the issue of positionality.

Conducting my research at the ENSP, one of the institutional homes of the country's sanitary reform movement, undoubtedly influenced my views about Brazil's pharmaceutical governance. Nonetheless, during my interviews, I maintained an

[7] More information about the process of obtaining approval by CEP/CONEP can be obtained at https://webspace.utexas.edu/mbf239/www/Brazilian%20Ethic%20Committee%20Documents/Guide%20to%20Brazilian%20Research%20Ethics%20Committees.htm.

inquisitive disposition that employed techniques ranging from devil's advocate to empathy—albeit towards understanding the concerns of AIDS patients or the realities faced by executives operating in a capitalist economic system. I also maintained that I was interested in learning about outcomes concerning state intervention in the economy and evolution of intellectual property laws. Despite jocular references that I worked for the CIA, I found most interviewees interested in expressing their views and describing their experiences to an outsider.

Interview strategies included a blend of semi-structured and open-ended techniques. Questions varied depending on each sub-group within the quota-sample. I developed a semi-structured questionnaire to guide the interview but included additional questions depending on the specific role of the individual in order to achieve depth into specific policy-making and production processes. After describing my research project and obtaining informed consent from the participants, I began the interview by asking the interviewees to describe their biography and then segued into specific questions. The interviews sought to elicit responses from participants about their perceived role in the policy-making process, the different social forces structuring social action, and the motivations of decision-makers at critical moments.

Data Analysis

The novelty of Brazil's response to the AIDS crisis lends itself to what Stake (1995) calls an "intrinsic case study." The case is not intended to be representative of all phenomena but is of particular interest to policy makers due to its achievements and to public sociology in terms of understanding a unique and successful outcome.

A case study allows for a close examination of contemporary phenomena in order to draw conclusions about the influence of current and past social structures (Stake 1995; Yin 1989). Applying ethnographic techniques in a case study allows a researcher to understand the cognitive dimensions and value orientations of actors as they challenge and reproduce structural forces. Case studies lend themselves to the "doubly-engaged social science" (Skocpol 2003:409) that allows the researcher to invalidate or confirm previous theories with empirical evidence while also generating new theoretical insights. Analysis of ethnographic data followed straightforward procedures of organizing field notes and transcripts into categories and common patterns and then re-ordering that the data into an outline (Fielding 2001).

Ethnography can be combined with power analysis, which focuses on the resources actors have at their command in order to achieve their objectives. These resources can be understood as economic, political, military, or ideological (Mann 1986). Power analysis has a long history in its application to developing countries, especially for those researchers working in the dependency paradigm (Gereffi 1983; Evans 1979).

Exploring the relations of power between groups in order to understand the causal factors leading to a particular outcome includes counter-factual analysis. Gereffi (1983: 70-71) describes this technique in the following way: "What is involved in this or any weighting procedure is a mental exercise in which the analyst removes the relevant casual factors one at a time in order to speculate what the world would have been like in their absence." The objective is to interrogate feasible alternatives derived from theory in the causal analysis of events in order to establish probabilistic generalizations. The method allows for the exploration of power relations between groups in society and external pressures exercised by foreign governments or corporations.

One caveat when using counter-factual analysis is to consider each situation in terms of rational choice theory. At each crucial juncture, actors make choices based on what they consider to be optimal outcomes given a certain set of conditions. While this approach may prove useful when considering negotiations between government officials and representatives of drug companies, it lends itself to overly deterministic explanations that underplay contest, contingency, and uncertainty (Goldstone 1998).

Validity and Reliability

Several strategies are used to enhance reliability and internal validity of my research. Since the investigator in qualitative research is the main research instrument and the filter on claims of reality, strategies to improve reliability and internal validity included peer review, member checks, declarations of researcher bias, and triangulation. Interviews with different sets of groups were used to increase the validity of how institutional connections are established and evolve through time. Findings derived from ethnographic techniques were triangulated with content analysis of previous scholarly and journalistic accounts.

External validity, or the generalizability of the findings, is restricted due to the limitations of a single case study. Additional research is required to assess the applicability of the findings to other cases. Brazil is considered as only the first case in a research project that includes India, South Africa, and Thailand.

PERIODIZATION AND DISSERTATION OUTLINE

My case study begins with a brief overview of the origins of Brazil's pharmaceutical industry prior to World War II in order to provide background to the changes in the country's political economy during the 1980s and 1990s. The next chapter provides this brief history of the Brazilian context in terms of the changes wrought by neoliberal policies and expansion of social rights. I detail the construction of "pharmaceutical citizenship" amidst efforts to establish a universal public health care system. The chapter identifies the actors involved in AIDS treatment policies and their roles in the political battles over intellectual property regimes in subsequent sections.

Most of the new empirical data I have gathered is divided into three periods. The first phase, from 1990 to 2001 (Chapter Three), begins with the local production of zidovudine (AZT) by the local private firm Microbiologica in the early 1990s. The period is characterized by the construction of treatment policies, especially the scale-up of the production of the first generation of ARVs in public labs. This period ends with the first confrontations between Brazil and transnational drugs companies (TNCs) over high prices. The first phase details the expansion of state capacity in response to the AIDS crisis. It also introduces the concept of "reputational dividends" to explain social alliances between state and social movements to contest corporate power.

The second phase, from 2002 to 2005 (Chapter Four), details problems in sourcing the key ingredients for producing second generation ARVs along with Brazil's aggressive negotiation strategy with TNCs. Despite several threats to issue a compulsory license, government officials do reach negotiated settlements. Domestic production of AIDS medicines, however, suffers setbacks due to increased dependency on imported and patent-protected medicines. This phase demonstrates the limits of civil society pressures to force state action due, in part, to weakened local production capabilities.

The third phase, 2006 to 2009 (Chapter Five), traces changes enacted during the second term of Luiz Inácio 'Lula' da Silva's presidency. The period is marked by the use of compulsory licenses and implementation of industrial policies in the health sector. State autonomy is strengthened through the implementation of industrial policies to support local production of strategic medicines. Chapter Five therefore details the institutionalization of the triple alliance between officials in the health ministry, local NGOs tied into transnational advocacy networks, and local private-sector drug companies.

Chapter Six summarizes my findings and their theoretical import. My hope is that that the reader will understand that the Agreement on Trade-Related Aspects of Intellectual Property (or TRIPS) has increased the structural power of transnational drug corporations to secure monopoly positions and weakened Brazil's public labs to quickly reverse engineer essential medicines. Pressures from global capital and US trade threats, however, did not lead to the demise of state autonomy. Rather, Brazil was able to contest TNCs by developing symbolic power, or "reputational dividends," based on successful social policies. By adroitly marketing its banner AIDS program under the discourse of human rights, health officials constructed a triple alliance between the state, the local bourgeoisie composed of national drug manufacturers, and local activist NGOs tied into transnational advocacy networks in order to contest global norms and pressures.

CHAPTER TWO – CONSTRUCTING PHARMACEUTICAL CITIZENSHIP AMIDST BRAZILIAN NEOLIBERALISM

Democracia serve para todos

ou não serve para nada.[8]

--Heberto "Betinho" de Souza, sociologist and activist

This chapter describes the transformation of the Brazilian pharmaceutical industry and its mixed successes in constructing universal health care policies during the 1990s. I argue that neoliberal reforms hail the dissolution of the development alliance between the state, local bourgeoisie, and transnational corporations. This "triple alliance" no longer serves the interests of transnational drug companies due to the end of activist industrial policy in the pharmaceutical sector, falling tariff barriers, and new protections on drug patents. As a consequence, state autonomy is constrained due to fewer policy tools available for market intervention, and the ideological commitment to market fundamentalism on behalf of the country's leaders.

While neoliberal reforms resulted in increased dependency in the pharmaceutical sector, problems associated with under-regulated drug markets and efforts to construct a universal health care system provide rationales for stronger state intervention. Toward the end of the 1990s, Brazil passed important laws to better police the drug market and support local generic production. The construction of a universal health care system, nonetheless, faltered because of a paucity of resources and a mobilized citizenry. One exception, however, is Brazil's AIDS program. Due to a strong coalition between health reformers and grassroots AIDS organizations, pharmaceutical citizenship is constructed along the lines of collective rights.

[8] "Democracy works for everyone, or it works for nothing at all."

Before detailing these changes, I will first describe how the global pharmaceutical industry operates. The objective of the review is to outline the incentive structure for policies geared towards the capitalistic production of pharmaceuticals and the origins of its power. Next, I provide a brief history of the pharmaceutical industry in Brazil, focusing primarily on policy changes during the 1990s such as trade liberalization, new laws protecting intellectual property, and the creation of a new regulatory body.

THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is unique in terms of its production, consumption, and regulatory oversight. Public authorities are responsible for regulatory oversight to assure efficacy, safety, and proper marketing of pharmacological agents. Few industries are subject to as many government regulations, ranging from overseeing clinical testing to end-user consumption.

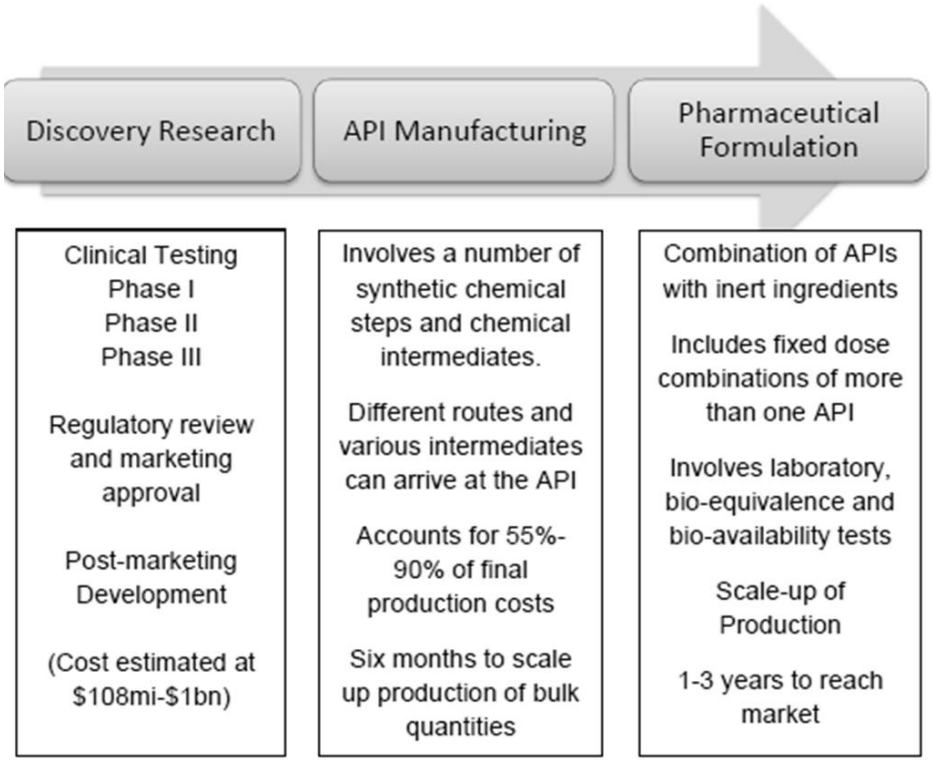
The development and production of pharmaceuticals can be divided into three distinct stages outlined in Figure 1. They include: 1) discovery research, 2) manufacturing of the active principal ingredient (API), and 3) pharmaceutical formulation. The first phase involves the basic science necessary to discover new pharmaceutical interventions up to the point of clinical testing. Basic research into a disease or ailment seeks to unveil its progression and causal mechanisms. By identifying therapeutic targets, researchers search for new chemical and biological compounds capable of arresting disease, endeavor provide relief from suffering, and/or cure a sickness.

To determine efficacy and safety, new drugs are tested in clinical trials that are divided into a number of phases with an increasing number of test subjects in each phase. After obtaining product approval by regulatory officials, clinical trials continue to identify adverse reactions through large-scale use by a diversified population. Research and development of new drug interventions is the most expensive, time-consuming, and the riskiest step in the pharmaceutical production process. It is also at this stage that an inventor applies for a patent.

The second stage in the production cycle is the mass production of the API and other raw materials, also known as pharmo-chemical production. "The synthesis of an API usually requires several chemical processing steps in which new chemical bonds are formed and molecular complexity increases," explains Pinheiro, Antunes, and Fortunak (2008), who review the cost structures of some of the most expensive and commonly used ARVs. The cost of the API represents between 55 to 90 percent of the direct manufacturing costs of formulated drugs (Pinheiro et al. 2005).

Manufacturing of the API also has the largest environmental impact. Producers begin with large quantities of chemicals. At each step of the production process, which may include fermentation, distillation, crystallization, among other techniques, chemicals are transformed and synthesized, and output becomes smaller and smaller until the active principal is obtained. Brazilian API manufacturers require about six months to scale-up production from laboratory to industrial level.

Figure 1: The Pharmaceutical Production Cycle



The third stage in the process is the development of the finished dosage form, or pharmaceutical formulation. This involves the mixture of the API with inactive ingredients in the form of capsules, pills, serums, and creams. The dosage of the API may vary to make a pill more or less potent, which determines the number of pills a patient is required per day. Improvements were made with the antiretroviral efavirenz, for example, with the dosage increasing from 200mg to 600mg so that, instead of three pills per day, patients need take only one. The fewer pills required, the better the adherence to treatment protocols.

Formulations with more than one API, called fixed-dose combinations, also reduce the number of pills required and improve treatment compliance. One of the first fixed-dose combinations of ARVs made available in Brazil was zidovudine (AZT) with

lamivudine. The development of formulations may take one to three years, and production occurs in tightly controlled environments to ensure purity and potency. Generic medicines are dosage forms that are comparable to reference drugs, or initial innovator drugs, based on bio-availability and bio-equivalence tests. These tests ensure that two drugs are the same in terms of how long the API remains in a patient's system and whether they result in the same therapeutic effect.[9]

Understanding the pharmaceutical value-added chain provides insight into the forms of power that firms and industry groupings may possess. These forms can be divided into two categories: patent power and market power. Patent power refers to the state codification of intellectual property used to provide the patent holder with market exclusivity. As sole provider of the drug, the patent holder or originator company can charge monopoly rents. Market power refers to firms' abilities to produce any node in the pharmaceutical value-added chain at a lower cost than their competition, either due to the uneven development of capitalism (cheaper wages) or government support (subsidies).

In analyzing Brazil's pharmaceutical sector, the focus will be on the API manufacturers (or pharmochemical sector) and drug manufacturers who produce the final dosage form. Pharmaceutical technology is the knowledge firms possess to combine active principals with inert ingredients for consumption. This know-how can be developed by passing through all the stages of the clinical testing of new compounds, or by reverse-engineering products available on the market to determine its chemical components and methods of fabrication.

[9] Brazil also has another class of drugs called *similars* that contain the same active ingredient in reference and generic medicines, but do not pass through the same quality control tests (see Homedes and Ugalde 2005).

R&D Costs and Patent Power

Patent power is intertwined with the particularities of the research and development (R&D) of new drugs. The main factor that distinguishes the pharmaceutical sector from other industrial pursuits is the large, upfront capital expenditures on R&D in order to identify new compounds with therapeutic properties.

The cost to produce and bring a new drug to market remains highly contested. Estimates at the high end, such as those produced by DiMasi and his colleagues (2005) at the corporate-financed Tufts Center for Drug Development, concluded that it costs $802 million dollars to research, develop and bring to market a new chemical entity. The figure includes the attrition rate and cost of capital. Other estimates are as high as $1.7 billion for the development of a new drug (Jim Gilbert, Henske, and Singh 2007).

These high estimates have not escaped scrutiny. Researchers at Public Citizen (2003) calculate R&D costs of $108 million per new drug. Adjusting for tax deductions on R&D expenses, the actual cost per new drug comes to $71 million. Bottom-up studies of specific innovator drugs place cost at $115 million to $240 million for new anti-tuberculosis drugs (Goozner 2004) and $208 million to $878 million for a new rotavirus vaccine (Light, Andrus, and Warburton 2009). The debate concerning the costs of drug discovery and development is complex and goes beyond the scope of this study.[10]

A strong intellectual property regime is particularly important for the pharmaceutical and chemical industries, since their products may be easily copied. The cost of reverse-engineering a product is far less expensive than the time-consuming process of discovery, research, and development of new therapeutic agents. Compared to

[10] To follow the debate see (Riggs 2004; Light and Warburton 2005; DiMasi et al. 2005; Goozner 2004; Angell 2004; Homedes and Ugalde 2006; Commission on Intellectual Property Rights Innovation and Public Health 2006).

the estimated $108 million to $1 billion cost to develop a new drug, interviewees in the field said that the budget to reverse engineer a new medicine and bring it to market is about $2.5 million (R$ 5 million).

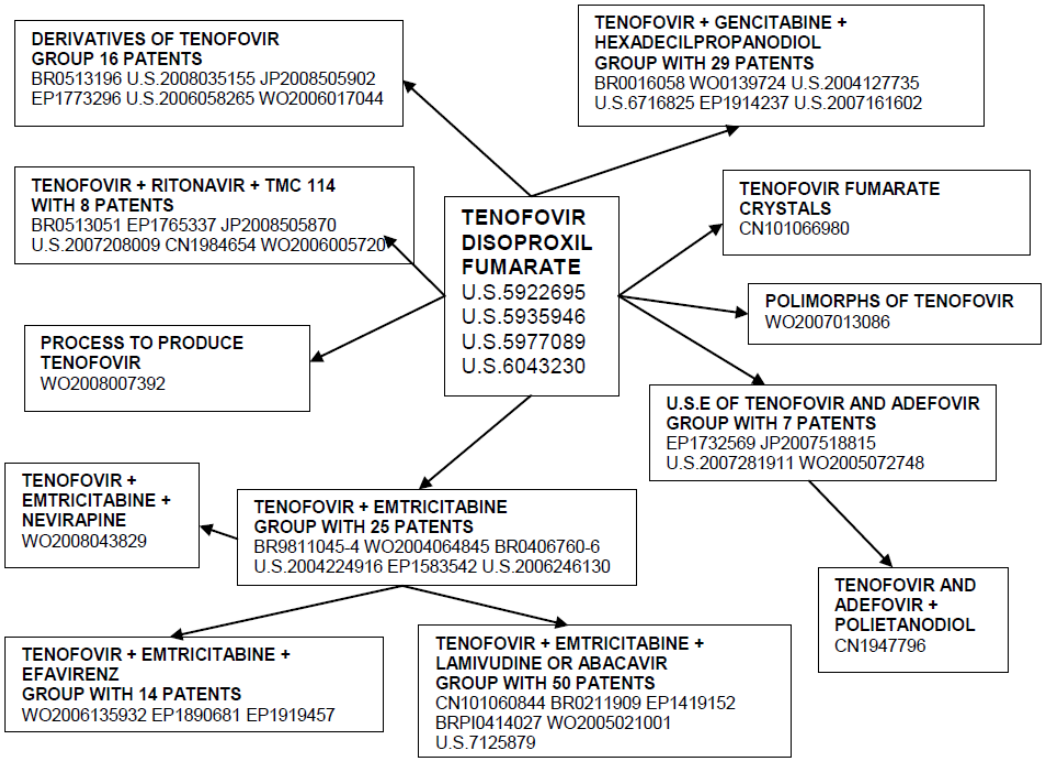
Patents have thus become an important tool for industry to secure monopoly rents based on the ability to charge prices 40-100 times the cost of production (Light 2008). Since the costs of developing new medicines remain high (although the exact cost is debatable), patents are viewed as a necessary economic incentive for attracting investment and dissuading competitors from simply copying new innovations. A patent is awarded when a claimant demonstrates novelty, industrial application, and a non-obvious inventive step of a new drug. In exchange for disclosing the invention, the state grants the inventor a set of exclusive rights for a limited period of time.

Critics of patents contend that the legal instrument involves more problems than societal benefits. Typically, patents do not provide all the necessary information to replicate an invention and are increasingly used as a end goal instead of as a means to innovation. Firms use patents to generate revenue via litigation even when they are not using them for production (Carolan 2009). The patent system also fails to direct resources into R&D for neglected diseases. According to the World Health Organization, "where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market" (Commission on Intellectual Property Rights Innovation and Public Health 2006: 32). Patents are criticized as an incentive mechanism so that companies can develop products for wealthy consumers, while diseases affecting the global poor receive less attention. The end result is that only 10% of total R&D expenditures are invested in diseases affecting some 90%

of the world's population, located mainly in developing countries (Commission on Intellectual Property Rights Innovation and Public Health 2006).

Employing various strategies to extend and control a drug market has lead to a veritable explosion of patents (Carlos Correa 2000). Figure 2 shows the various patents connected to the AIDS medicine tenofovir marketed by US-based Gilead Sciences. The figure shows patents on fixed-dose combinations, derivations, polymorphs, processes, and uses. Without entering into technical details concerning each family of patents, Table 2 reveals the complexity related to different patent strategies and the lengths companies go in order to extend patent monopolies and thus reduce competition.

Figure 2: Explosion of Patents for Tenofovir



Source: Brasil (2008a)

TRIPS and Humanitarian Safeguards

The creation of the World Trade Organization (WTO) in 1995 allowed for the extension of patent power to the rest of the world. The Trade Related Intellectual Property System (TRIPS), one of the pillars of the WTO, establishes patents as part of an overarching international legal code. The accord establishes a minimum baseline of intellectual property protection that all WTO members must include in their national legislation. The agreement stipulates that a patent holder is guaranteed exclusive rights for the exploitation of product, process, and use over a specified period of time. Minimum obligations are a patent period of twenty years for pharmaceuticals and no discrimination against the patent rights of foreigners.[11]

TRIPS also provides humanitarian safeguards for members when formulating national legislation. Article 8 states that countries may adopt "measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development" as well as take additional action "to prevent the abuse of intellectual property rights by right holders." The Doha Declaration of 2001 reaffirmed the rights of WTO member states to circumvent patents in order to uphold public health obligations. (Chapter Three describes Brazil's efforts in establishing the Doha Declaration and its relevance to country's confrontations with transnational drug companies.)

The main legal instrument for correcting abuses by patent holders is the compulsory license (CL), which allows for the exploitation of a patent by third-parties

[11] Article 7 states the objective of the accord: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

without the consent of the patent holder. TRIPS foresees the use of a CL in three main instances: national emergency, cases of anti-trust, and for public, non-commercial use. Before issuing a CL, a government must first attempt to reach a negotiated settlement with the patent holder, who, in the case of the CL, still has the right to receive royalties. Only in cases of national emergency and public, non-commercial use can governments dispense with prior negotiations (Carlos Correa 2000) .

While TRIPS establishes a minimum baseline of patent protection of twenty years, states still retain a degree of maneuverability in terms of compliance and criteria used for adjudicating patentability. In terms of transition periods, high-income countries had until 1996 to change their laws; middle-income countries, 2005; and least developed, 2016. The more time developing countries have to adjust their patents in accordance to TRIPS, the more their generic pharmaceutical industry will have opportunities to legally reverse-engineer drugs patented elsewhere. India and China waited until 2005 to change their intellectual property laws, while Brazil anticipated the deadline by nine years.[12]

Domestic intellectual property legislation may incorporate a number of humanitarian safeguards outlined in TRIPS in order to protect domestic health care systems and markets from abusive market practices. These include the use of CLs and parallel importation[13]. States can also determine which government organizations can grant patents, whether other public or private organizations can participate in the analysis of patent applications, as well as determine narrow versus broad definitions of

[12] The reasons why Brazil reformed its IP laws before the TRIPS deadline are addressed below.

[13] Parallel importation allows countries to perform price arbitrage for the same patented product placed in both foreign and domestic markets. When this TRIPS flexibility is incorporated in national legislation, the domestic country can import a patented product that may be cheaper on a foreign market. The patent holder, once placing the patent on the foreign product, has exhausted her/his marketing rights to resale on the domestic market.

patentability. Patent offices, for instance, may take into account public health concerns when issuing patents on medicines and diagnostic equipment.[14]

National IP laws sometimes go beyond TRIPS minimum requirement as long as such laws are consistent with the international agreement. Indeed, many countries have embraced numerous TRIPS-plus measures; that is, they fail to incorporate all the proscribed safeguards, either due to domestic political considerations or as a result of bilateral or regional trade agreements that demand more restrictive IP laws[15] (Smith, Carlos Correa, and Oh 2009).

TRIPS institutionalizes power differentials between wealthy and poor countries, whereby the former with developed IP infrastructures and cultures has a clear advantage over the latter (Carolan 2009). Before TRIPS, countries decided the level of intellectual property protection they deemed compatible with their level of development. Most countries, even while respecting patents in other industries, did not provide patents for pharmaceuticals since they were considered a strategic input for the health system. The accord reduces the policy space available for developing country governments so that they cannot replicate the successes of developed countries (Wade 2003; Chang 2002).[16]

The Global Pharmaceutical Industry

Patent power is one of the many strategies originator companies employ to maintain market share and high rents. The increasing salience of patent power is

[14] For a public health perspective on patentability outlined by Argentine economist and lawyer Carlos Correa, see WHO/ICTSD/UNCTAD (2006).
[15] The US, for example, has pushed for more restrictions on the use of compulsory licenses in bilateral trade negotiations
[16] For reviews on the history of IPR and TRIPS see (Matthews 2002; Richards 2004; Sell 2003).

associated with the uneven development of pharmaceutical production across the world. Incumbent pharmaceutical corporations from wealthy, industrialized companies have pushed a global patent agenda in order to arrest the rise of cheap, generic producers from the developing world that are able to exploit their market power based on less expensive production costs.

While the debate on the costs of bringing a new drug to market will continue, the survival of capitalist drug firms depends on large upfront investments on R&D and marketing. Large capital expenditures necessarily impact market structure. Compared to other industries, wide scale competition in pharmaceuticals practically does not exist between producers, except when a patent expires and generic manufacturers enter the market. Instead, the global pharmaceutical industry remains heavily oligopolistic with companies concentrating in product differentiation within specific therapeutic classes. This is observed even in the ARV segment, when, for instance, Roche decided to exit the ARV industry while other companies such as Merck and GlaxoSmithKline (GSK) expanded their portfolios in AIDS medicines.

Another strategy employed by pharmaceutical firms to protect and extend market control over product creation and sales is industry consolidation through mergers and acquisitions. GSK and Pfizer recently decided to establish a strategic alliance in their ARV divisions. Bermudez (1995) estimates that the planet's ten largest pharmaceutical firms controlled 40% of the world market during the 1990s. Since that time mergers and acquisitions have continued resulting in the approximately 100 largest companies in the world being responsible for 90% of all the pharmaceutical products for human use. Around 75% of sales are concentrated in developed countries like the United States, Western Europe, and Japan.

IMS Health (2008) forecasts that the global pharmaceutical market reached $735 billion in 2008. Market analysts predict stronger future growth in emerging markets such as China, Brazil, and India compared to developed countries, which is one of the reasons for the push to have these emerging markets adopt patents. Table 1 lists the top 20 largest pharmaceutical companies in the world according to total sales in 2006. It is noteworthy that the sales of the top eight firms were larger than the entire budget of Brazil's Ministry of Health for the same year:

Table 2: Global Company Sales Summary (Millions US$) in 2006

Rank	Company	Sales	Market Share %	Sales Growth
1	Pfizer	45,083	8.6	1.8
2	GlaxoSmithKline	36,947	7.1	8.9
3	Sanofi-Aventis	35,605	6.8	4.9
4	Novartis	28,868	5.5	17.9
5	Roche	26,560	5.1	21.4
6	AstraZeneca	25,741	4.9	10.5
7	Johnson & Johnson	23,267	4.4	4.2
8	Merck & Co	22,636	4.3	2.8
9	Wyeth	15,683	3.0	9.8
10	Eli Lilly	14,816	2.8	7.5
11	Bristol-Myers Squibb	13,861	2.6	(9.1)
12	Amgen	13,858	2.6	15.3
13	Abbott	12,395	2.4	(6.8)
14	Boehringer Ingelheim	10,401	2.0	15.2

Source: Wood Mackenzie's Productview™ March 2007

The world's largest pharmaceutical companies increasingly operate on a global scale and executives plan their strategies at this level, but local distribution and marketing continues to segment markets into national domains due to differing national regulations and health care systems. Nonetheless, lobbying efforts tend to be concentrated in the

United States. According to the Center for Responsive Politics (2010), between 1990 and 2008 the pharmaceutical industry contributed around $170 million to federal political campaigns. Lobbying the US government is important for the industry to protect its most lucrative market and to win a powerful backer to enforce its patent rights around the world.

Research on the global pharmaceutical industry highlights current factors driving their growth and activities. First, the wave of mergers and acquisitions the industry has experienced in recent decades stems, in part, from widespread overcapacity and capacity underutilization as a result of local production in the 1970s and 1980s. The tendency is to centralize production of active ingredients and de-centralize end production and marketing (Zeller 2000). Furthermore, centralization has led to increased intra-firm trade between separate branches of the same company.

Second, global drug companies tend to out-source production less relative to other industries. The one exception is in research and development. Large firms increasingly concentrate on marketing and distribution of final products while outsourcing R&D activities to small-biotech companies and clinical testing to contract research organizations (Homedes and Ugalde 2006; Tarabusi and Vickery, Graham 1998).

Third, pricing of patented medicines is carried out secretly by top executives and hired specialist consultants. Light (2008: 67) explains the pricing system: “The value of a new drug is made up of the reference value, the price of the best alternative, and the added or differential value of the new drug” [italics in original]. The added or differential value includes all the advertising and marketing techniques employed to convince doctors and patients that a specific drug is the best and has few side effects.

At the global level, prices of the same drug vary considerably, even in the developed world. In the US, for instance, insurance companies negotiate with drug

companies whereas in Canada and the United Kingdom, a pricing board negotiates with the drug firms. In the developing world, prices also vary considerably according to market competition, patent regimes, and public health systems (Silverman, Lydecker, and Lee 1992). In response to the HIV/AIDS epidemic, large drug companies established a differential pricing system that sets pricing criteria for each country according to its level of development (high, middle, or low income as determined by the World Bank) and its HIV/AIDS prevalence rates. High income countries with the lowest prevalence rates are charged the highest prices, while low income countries with prevalence rates over 1% receive ARVs at the cost of production.

Lastly, the rise of India and China as important producers of medicines and raw materials has shifted market power away from Western firms. Over the past 30 years, India in particular has become a powerhouse in producing generic medicines, and its firms such as Cipla, Ranbaxy, and Aurobindo have become leading suppliers of inexpensive global AIDS medicines. The growing market power of Indian and Chinese firms has been able to undercut not only established pharmaceutical firms from the First World but also Brazilian pharmaceutical companies.

Established firms have responded by acquiring Indian firms, such as Japan's Daiichi Sankyo buying a controlling stake in Ranbaxy as well as by establishing more partnerships in raw materials outsourcing and R&D initiatives. One continued concern, however, is the supply of cheap, generic alternatives after India and China adjusted their legislation in 2005 to make them TRIPS-compliant in 2005. The current forecast is that firms from China and India will continue to supply cheap, finished drugs and bulk raw materials, but newer medicines will no longer be available at inexpensive prices, or perhaps at all (Grace 2004). Patent restrictions could thus stem the flow of future AIDS medicines at affordable prices.

Pharmaceutical production is a complex, high-tech industry that involves different forms of patent and market power. The growing division of labor in the global pharmaceutical industry continues apace as low-cost Asian producers advance in global markets, but R&D remains concentrated in developed countries, especially in the bio-tech offshoots from university labs. Clinical trials of new therapies, meanwhile, are undertaken throughout the world. While this overview does not detail every aspect of the pharmaceutical industry's operations, it does provide an introduction to how the sector works and a background to its operations as we examine the case of Brazil.

THE PHARMACEUTICAL INDUSTRY'S INSERTION IN BRAZIL

According to IMS Health—World Drug Purchases (2008), the Brazilian pharmaceutical market ranked as the ninth largest in the world in 2007. Market sales reached $12.2 billion or 2.91% of world total. The country is home to 550 pharmaceutical companies that employ 69,000 people (Grupemef/Febrafarma 2007). Studies of Brazil's market reveal that 48 companies are foreign-based but are responsible for between 70-80% of the entire Brazilian market; 18 public labs account for less than 5% (selling mainly to the public health sector); and the rest in the hands of local, privately-owned firms (Hasenclever 2002; Palmeira and Pan 2003), which vary in terms of size and markets. The Brazilian company Aché is the largest drug firm with 6.94% of the market, ahead of France's Sanofi-Aventis, with 6.81% (Gadelha 2007).

The Brazilian pharmaceutical industry is highly sophisticated in its ability to produce end products in a variety of formulations. Few national firms have vertically integrated production, and foreign firms with local operations focus on end-stage

production and marketing of their products. Investments in research and development, as well as new products and processes, remain embryonic.

Given its weak pharmochemical sector, Brazil remains heavily dependent on imported chemical intermediates and APIs used in drug formulations. Currently, there are only 23 firms in Brazil that produce active principals and intermediates, and these account for only 20% of the domestic market—that is, the remaining 80% used in Brazilian pharmaceutical production is imported. China and India together provide about 20% of inputs on the national market. In 2006, medicine imports of$1.742 billion surpassed exports of $435 million; and imports of APIs amounted to $1.268 billion compared to U$272 million in exports (Gadelha 2007). The combined trade deficit of $2.3 billion continues to stimulate policy makers' attempts to reduce external dependency.

Brief History of Brazil's Pharmaceutical Industry

The current situation of dependency in the Brazilian pharmaceutical sector stems from the penetration of foreign capital and from several unsuccessful attempts by the state to encourage the development of the domestic industry. Bertero (1972) recounts how the first private Brazilian pharmaceutical firms were established in the 1920s and 1930s and largely resembled their counterparts in the United States, but now after World War II, local firms declined as the government began providing incentives to attract foreign investors. Meanwhile, US and European firms began to internationalize their operations. Local firms lagged behind foreign competitors due to lack of access to

capital, technology, and managerial skills, as well as the absence of ties between universities and the private sector (Bertero 1972).

During Brazil's period of import substitution, high tariffs resulted in a considerable build-up of the sector, but with no controls on the activities of transnational firms to operate in Brazil, acquisition of private national drug companies became the main strategy for foreign firms to enter the market. Between 1958 and 1972, the control of forty-three private Brazilian labs was transferred to multinational drug companies who increased their share of Brazil's domestic market from 14% in 1930 to 73% by 1960 (Bermudez 1995).

In the decades leading up to the neoliberal reforms of the 1990s, Brazil enacted a number of policies to stimulate local production. First, a number of state governments and universities opened public, or government-affiliated, labs to produce medicines for the public health sector and to respond to outbreaks of tropical diseases (Flynn 2008). The Institute in Technology of Medicines (Instituto de Tecnologia em Fármacos—Farmanguinhos), created in 1956 with financial assistance from the US government, operates under the direct control of the federal Ministry of Health and comprises part of the Oswaldo Cruz Foundation (Fundação Oswaldo Cruz – FioCruz) medical and health complex, similar to the National Institute of Health in the United States.[17]

In 1971 the military regime created the Central Medicines Agency (Central de Medicamentos—CEME) to develop policies for the sector and centralize public procurement of medicines from both public and private labs with the aim of developing the country's pharmaceutical base. CEME was also responsible for collecting regional

[17] One former Farmanguinhos director called FioCruz "the NIH of the poor" since it focuses on researching diseases that affect developing countries such as Brazil but with a much smaller budget (Personal communication, Eloan Pinheiro, 2 June 2006).

epidemiological information, promoting research and technological development, as well as controlling and assuring quality (Bermudez 1995).

The second pre-curser to the 1990s was a change in the Brazilian Industrial Property Code in 1969 eliminating patents for the pharmaceutical sector, until the current Industrial Property Act passed in 1996. The policy was designed to help build up the country's local pharmaceutical industry by allowing for the lawful copying of existing drugs.

The third major government initiative aimed to develop the fine chemicals and pharmochemical industries in order to reduce foreign dependency on imports. Import substitution policies led to the development of a base chemical and petro-chemical industry as well as the production of finished dosage forms, but the intermediate stages in the production cycle (i.e. phase two in the graph above) remained weak or altogether missing.

Consequently, the government began to enact policies to attract investments so as to build up the fine chemical industry that produces specialized chemicals for the production of active pharmaceutical ingredients (APIs) and their intermediates, as well as for fertilizers. The Ministries of Health and of Science and Technology provided a number of incentives for the production of APIs and chemical intermediates. The decades preceding the 1990s represents the ideal form of Evan's "triple alliance" between the state, multinational capital, and local bourgeoisie (Evans 1979).

In response to sluggish economic growth, hyperinflation and growing indebtedness, policy makers implemented a set of neoliberal policies during the 1990s aimed at curtailing the government's role in the economy. Political elites, pressured by international financial agencies and motivated by ideas of a minimalist role of the state, believed that privatization of public assets and increasing competition from foreign

imports would improve the government's deteriorating fiscal position and improve economic productivity. Public support for drastic measures stemmed from the need to stabilize the economy, which was suffering from hyperinflation and heavy foreign debts (Weyland 1998).

President Fernando Collor (1990-1992) adopted the Washington Consensus set of market-oriented policies, marking the end of ISI policies. The government slashed tariffs on imports, removed price controls on medicines and abandoned industrial policies. As tariffs on APIs and fine chemicals fell from 65% to 20% due to WTO agreements and privatization of state petrochemical firms, several upstream plant that had been established to produce APIs were phased out. In the first half of the 1990s, 1,700 production lines of synthetic intermediates and inputs were shut down (Orsi, Hasenclever, Fialho, Tigre, and Coriat 2003). The consequence was evident in the sector's trade balance: imports of drugs and APIs climbed from $512 million in 1990 to $2.363 billion in 2002, while exports remained at just over $400 million during the same period (Palmeira and Pan 2003).

The Industrial Property Act of 1996

Neoliberal efforts culminated in the approval of new intellectual property legislation in 1996. The Industrial Property Act reinstated patents for pharmaceutical processes and products. When drawing up legislation regarding intellectual property, policy makers did not wait until the 2005 deadline set for middle-income countries to adhere to TRIPS. Among the reasons for early compliance with TRIPS were US pressures, which had begun during 1980s (Nunn 2007; Tarchinardi 1993). In 1988, for

instance, President Reagan used Section 301 of the Trade Act of 1974 to impose a 100 percent tariff on imports of Brazilian paper products, consumer electronics, and Brazilian medicines.

In the view of Brazil's ambassador to General Agreement on Tariffs and Trade (GATT), Rubens Ricupero, the US could never prove that its pharmaceutical companies were losing profits due to the lack of patent protection on pharmaceuticals. Furthermore, he maintained the unilateral trade sanctions were illegal under international trade law. "We lost out because of power politics," he said (Ricupero 2007) . The ambassador suggests that the US' strategy was to pressure Brazil on intellectual property in order to obtain concessions from other countries like India and China.

Brazilian policy makers began discussing a new patent law in the early 1990s, but passage of Act #9.279 did not occur until May 15, 1996. Delays in approving the law stem from political changes in the Brazilian presidency, as well as resistance by public health advocates, known as sanitaristas. One important group that was unaware of the implications of the new patent legislation were AIDS activists (Nunn 2007). Without the input of public health advocates who did not have the backing of AIDS activists or other mobilized sectors of civil society, new IP legislation had few of the flexibilities outlined by TRIPS that were designed to protect consumers and curtail industry abuses.

In an interview with Nunn (2007), Fernando Henrique Cardoso, Brazil's president at the time of passage and chief sponsor of the legislation, refused to comment on his motivations for pushing the bill, but two factors stand out. First, Cardoso and other members of his economic team believed that embracing IPR would be a positive step for Brazil's economic liberalization, reduce Brazil's dependence on technology imports, and attract foreign investment (Nunn 2007; Palmeira and Pan 2003). Second, policy makers believed that IPR would improve trade with the US. Since many members of congress are

tied to the export-agriculture industry in Brazil and the US is one of the main destination markets, deputies and senators were susceptible to US trade threats. Representatives from the Fine Chemical and Pharmochemical Trade Association (ABIFINA) see US pressure behind a bill that incorporates few of the safeguards outlined in the TRIPS accord.[18]

Contrary to policy makers' belief that increased protection of intellectual property would encourage more investment, foreign companies scaled back domestic activities (except in marketing and end-stage production). Six years after the Industry Property Act was passed, Brazilian firms accounted for only 3.1% of the industry's total 6934 patent claims. The vast majority have come from countries that are home to the world's leading pharmaceutical companies (Bermudez and Maria Auxiliardora Oliveira 2004).

Modifications have been made to intellectual property laws since 1996 as a result of AIDS activism and the development of a domestic triple alliance. Before recounting the origins of these coalitions, it is necessary to describe the political climate pertaining to pharmaceuticals at the end of the 1990s.

ANVISA and The Generics Act

The promotion of neoliberal pharmaceutical policies came to a halt at the end of the 1990s as society demanded re-regulation of the sector. A veritable crisis in the pharmaceutical market due to price hikes and falsification of products gained the media's

[18] "The initial bill was approved by consensus in the House of Deputies in 1993-1994 and was very good—ABIFINA had taken part in the negotiations with (then President) Itamar Franco and (then Minister of Foreign Relations) Cardoso. But when it went to the Senate, which at the time Cardoso had become president and had other commitments, the bill changed form. Because of pressure from the US, such as in 1995-96, Lampreia, the Minister of Foreign Relations, warned that if Brazil did not pass the TRIPS-plus legislation, there would be trade sanctions on steel, orange juice, among items," said Brasil (2008b), executive vice-president of ABIFINA.

spotlight resulting in a Parliamentary Investigative Committee on Medicines [Comissão Parlamentarde Inquérito Desinada a Investigar os Reajustes de Preços e a Falsificação de Medicamentos (2000)] in November of 1999. Although the high-profile congressional investigation did not result in heavy penalties, media attention led to renewed government intervention in the pharmaceutical sector, including the creation of a powerful regulatory agency and legislation governing generic drugs.

In 1999, Brazil passed Law #9.782 that created the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária—ANVISA), modeled after the United States' Food and Drug Administration (FDA). The new agency represented the start of a new regulatory system for medicines, as well as for food and other areas of sanitary surveillance. Since the mid-1980s, health professionals had been demanding the creation of an agency that would have administrative independence and financial autonomy. Drug companies interested in protecting its brand names also lobbied for a strong enforcement agency to investigate issues of fraud.

Besides approving registrations for the commercialization of pharmaceutical products and inspecting factories at home and abroad, ANVISA has additional responsibilities, such as monitoring and controlling prices of certain drugs and medical inputs. In 1999, a Presidential Directive (Medida Provisória) determined the National Institute of Industrial Property must consult ANVISA before conferring a patent. Policy makers decided that the patent office did not have the expertise to analyze patent claims for drugs, especially to ensure that the novelty requirement is truly satisfied. The change has resulted in a turf war between the two regulatory bodies and a large backlog in patent approvals. As of the date of this writing, PhRMA and the US government continue to pressure their Brazilian counterparts to address the situation.

The last major policy initiative of the 1990s was the Generics Act of 1999. The law established the conditions for licensing as well as technical standards and norms for reference, innovative, generic, and similar drugs. While both generics and similars are copies of off-patent medications, only generics have passed tests of bioavailability and bioequivalence. This means that although both types of medicines contain the same active principle ingredient, only generics are proven to be interchangeable to the reference or innovator product in terms of safety, efficacy, and quality.[19]

The Brazilian transnational pharmaceutical companies association, INTERFARMA, lobbied against the legislation and launched campaigns aimed at consumers and physicians questioning the quality of generic medicines (Bermudez and Maria Auxiliardora Oliveira 2004). Foreign firms rightly feared the loss of market share, for according to the generic pharmaceutical association Pro-Genericos, generic medicines now account for 19.6% of the entire market, up from zero when the legislation was passed. Of this amount, Brazilian companies account for 88% of sales (Pro-Genericos 2009).

Even before the Brazilian government began to confront transnational drug companies over the high prices of AIDS medicines and patent protections, there was increased societal distrust of the industry. The investigations and new legislation illustrate the rise of state autonomy based on democratic pressures from below and market irregularities from above.

Brazil's pharmaceutical market remains dominated by transnational drug companies. The strengths of its nationally-owned pharmaceutical industry lie in commodity generics, conventional dosage forms, and some value-added and branded

[19] Producing generic medicines of chemical drugs is technologically easier than making copies of biologic-based medicines.

generics. A weak domestic pharmochemical sector however is considered to be the Achilles' heel of the Brazilian pharmaceutical sector. This is also the case in terms of producing ARVs. Despite highly trained engineers and competent scientists, discovering new chemical entities and treatments remains the prerogative of foreign companies and institutions.

In addition, neoliberal policies increased the dependency of Brazil's pharmaceutical sector. The end of state support and patent protection marked the dissolution of the development alliance between the state with local and foreign capital. Trade liberalization and market de-regulation of the pharmaceutical sector resulted in a societal backlash that demanded more state intervention. Public policies which came from this rising form of pharmaceutical citizenship, however, occurred most prominently with AIDS. The next section details the changes in public health polices during the 1990s and exceptionalism of HIV/AIDS in the health care system.

THE BRAZILIAN STATE'S FEDERAL HEALTH COMPLEX

Reforms to the Public Health Sector

Brazilian social policies have undergone significant changes since the transition to democracy in the second half of the 1980s. The development model implemented under military rule (1964-1985) resulted in income concentration and minimal attention to social needs (Burity 2006). Elites integrated subordinate social groups, such as labor unions, into the governing apparatus under corporatist principles. Access to health care was determined by a welfare regime based on occupational status in which formally employed groups (especially high income groups) had access to sophisticated levels of

health care while marginalized populations and the un- and underemployed received inadequate care and treatment. Furthermore, public administration was inefficient and corrupt and was thus viewed as part of the problem instead of part of the solution (Bresser-Pereira 1999).

Popular resistance to the military dictatorship flourished in the late 1970s and on into the 1980s. It is important to highlight the development of numerous democratic movements with shared common interests in reforming state-society relations based on notions of participation and human rights. One important group that had an impact on the structure of the country's health sector is the sanitary health reform movement. These activist physicians and health care workers, known as sanitaristas, penetrated government bureaucracies and have played an important role in demanding and carrying out reforms of the country's health infrastructure since the 1970s (Berkman et al. 2005; Paulo Teixeira, Vitória, and Barcarolo 2003; Weyland 1995).

A coalition of santaristas and progressive forces established health as a human right guaranteed by the state in the country's new constitution of 1988. During the 1990s, the government adopted a number of reforms that resulted in the creation of a two-tiered system. First is a system of universal public provision geared towards the general population and known as the Unified Health System (Sistema Único de Saúde—SUS). The second system consists of private hospitals and insurance policies that cater to the middle and upper classes, although SUS also contracts a number of services from private hospitals. The 1990 Federal Law on Health established the principles of SUS: universality (health is everyone's right), integrality (health problems of both individuals and the collective are treated in their entirety), and equity (everyone has the equal opportunity to use the public health system irrespective of social class).

SUS' operational principles include decentralization and social participation. To this effect, the public health system has been decentralized to twenty-six states and 5508 municipalities, and health councils have been established at the municipal, state, and federal levels to make decisions, provide directives, and monitor actions. Despite achieving important health reforms, many sanitaristas believe that SUS has failed to live up to its ideals. Creating a universal health care system faltered due to resistance from clientalistic politicians, bureaucracies controlled through lines of patronage, and neoliberal initiatives aimed at removing the state from the economy (Weyland 1995; Celia Almeida et al. 2000).

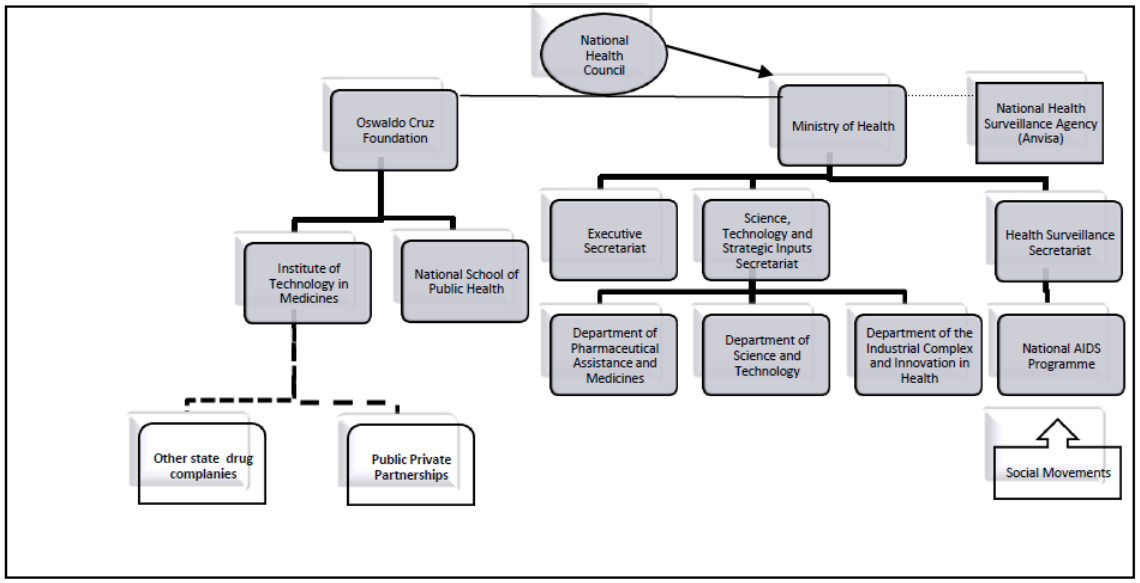
Ensuring health equity remains a challenge for SUS due to underfunding, regressive taxation, and unequal distribution to the country's diverse regions (C Almeida et al. 2000). In a recent interview, Jadib Jantene, former Minister of Health during the 1990s, said that SUS should have a budget of R$ 120 billion a year, but current amounts barely reach R$ 50 billion (Martins 2008). While SUS provides access to 90% of the population and 29% rely exclusively on the public health system, some 40 million middle and upper class Brazilians purchase additional health care through private insurance plans. Extending SUS coverage and improving service delivery continues to strain budgets and limit what can be spent on other programs such as the purchase of expensive medicines to treat people with HIV/AIDS.

Despite its fragilities, the Brazilian state's federal health complex has a number of important actors and strategic assets to address domestic health crises, respond to civil society pressures, and overcome technological obstacles (see Figure 2). The Minister of Health oversees a number of secretariats, including the executive health secretariat that negotiates contracts and pays expenses. The Science, Technology and Strategic Inputs Secretariat, created in 2003, formulates pharmaceutical policies, while the Department of

Pharmaceutical Assistance administers policies, coordinates procurement, and investments in the country's network of eighteen public (state-owned) labs.

The Department of the Industrial Health Complex has taken an increasingly important role in formulating industrial policies and encouraging the local production of inputs used by SUS. As regulator of the sector and enforcer of quality control, ANVISA is formally part of the Ministry of Health but politically insulated given its financial and decision-making autonomy. Lastly, FioCruz is South America's largest health research complex, home to technical schools and numerous research institutes, including the Institute of Technology in Medicines (Farmanguinhos). The pharmaceutical laboratory produces medicines for SUS and is directly subordinated to the Ministry of Health (Flynn 2008).

Figure 2: Brazilian State Health Complex (federal level, selected bodies and institutes)

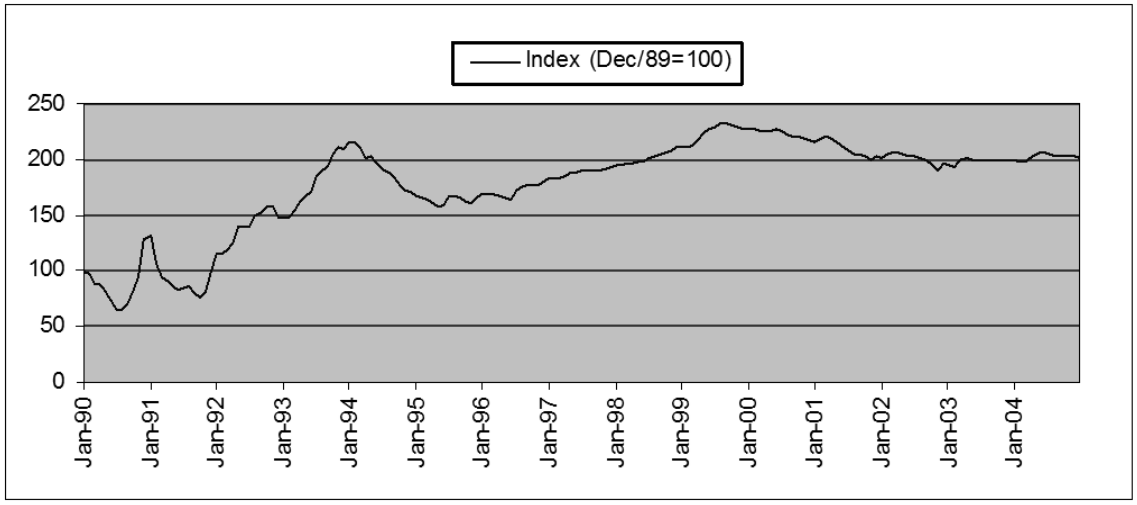


Pharmaceutical Policies

Over the course of the ten years between 1989 and 1999, drug prices rose fifty-four percent above inflation while per capita consumption fell (Ministry of Health 2000). Graph 1 illustrates the impact of price liberalization on consumer prices. Despite early volatility, prices doubled between 1992 and 1994, only to fall after 1994 due to the introduction of a new monetary plan.

Price increases continued until the turn of the century but have levelled off due to new government price regulations. Obviously, in a country with widespread inequality, consumption varies greatly according to income strata. One sector analysis estimated that by the end of the 1990s, forty percent of the Brazilian population from lower income brackets did not have sufficient resources to purchase medicines at retail pharmacies (Callegari 2000).[20]

Graph 1: Evolution of the Price of Medicines deflated by INPC consumer price index



Source: Ministry of Health

[20] Purchasing medicines at high prices not only impacts lower income sectors of the population, but also affects adherence and propensity to purchase fake medicines.

Brazil enacted a number of pharmaceutical policies in the 1990s to keep in step with the construction of SUS. The first of these was the closure of CEME in 1997. Government attempts to use CEME and public labs to develop the country's pharmaceutical industry–especially the development of upstream activities, such as fine chemicals and production of raw materials–fell short of their stated objectives (Bermudez 1995; Ministry of Health 2002). Instead of organizing and streamlining the country's network of public labs, CEME's activities revealed the conflicts between the public and private sectors, especially with regard to centralized purchases of medicines. Acquisitions increasingly came from private companies at the expense of public labs due to the hegemonic position of foreign firms in the domestic market and increasing corruption at CEME (Bermudez 1995; Ministry of Health 2002).

CEME's closure symbolizes the end of the "triple alliance" in developing the pharmaceutical industry but also frees up the state to pursue a more autonomous trajectory in its pharmaceutical policies. With the closure of CEME, the Ministry of Health's lab, Farmanguinhos, became responsible for federal medicine purchases and distribution, and state governments stepped up programs to serve the public health sector (Cosendey et al. 2000). By the end of the 1990s, the Ministry of Health drafted new policies for supplying pharmaceuticals through SUS, including an updated list of essential medicines, minimum levels of care, and decentralization of basic pharmaceutical services. In terms of financing, the federal government would contribute 50% of the budget, and state and municipal governments would each provide 25%.

With the presidency of Luiz Inacio 'Lula' da Silva starting in 2003, the Ministry of Health has increased expenditures on medicines and investments in public labs, as well as initiated industrial policies for the sector. Table 1 shows that federal expenditures on medicines increased from R$ 1.9 billion in 2003 to a proposed R$ 4.7 billion in 2007, and

spending has increased in all categories. For "high cost medicines," outlays have increased by R$ 1 billion, and the costs of AIDS medicines have nearly doubled in the five year period. During the 2002-2006 period, federal spending on medicines jumped 124% versus a 9.6% increase on total health outlays (Ministry of Health/Secretaria Executiva 2007).[21]

Table 3: Expenditures by the Federal Government on Medicines (in R$ millions)

Area	2003	2004	2005	2006	2007*
Medicines for Strategic Programs	231.6	790.3	681.0	690.0	721.1
Basic Medicines	176.8	248.5	228.0	290.0	315.0
High Cost Medicines	516.0	813.8	1,147.4	1,355.0	1,580.0
Medicines for AIDS/STDs	516.0	516.0	550.0	960.0	984.0
Vaccines	250.0	480.6	550.0	750.0	783.8
Drugs for blood-clotting diseases	222.0	207.8	223.0	244.0	280.0
Medicines Total	1,912.4	3,057.1	3,379.4	4,289.0	4,663.0
Investments in Public Labs	36.0	80.1	63.6	71.0	74.7
Investment in Research and Development of Strategic Inputs	14.4	66.6	68.4	75.3	85.4

Source: Brazil (2007) Department of Pharmaceutical Assistance (SCTIE/MS)
* Proposed Ministry of Health budget

During the past two decades, Brazil has achieved much progress with the implementation of a new universalistic health care regime. Before, only the formally employed had access to quality care, while the un- and underemployed relied on

[21] One factor contributing to larger outlays on medicines are lawsuits against the government by patients and patient associations demanding free medicines. Many of the cases have been won by the plaintiffs.

charitable organizations. Despite the increase in funding and consolidation of health programs, Brazil's public health system continues to suffer from inadequate care, long lines, and shortages of basic medicines, and attaining the principles of SUS—universality, integrality, and equity—remains elusive.

Access to health care in Brazil follow the changing ideas of citizenship and social policies in Latin America as a whole in which welfare stratification is tied to differences between private and public health care (Roberts 2005). The one exception, however, is the National AIDS Programme (NAP).

The Development of the National AIDS Program

It is commonly said that if you are living with HIV/AIDS in Brazil, you receive special treatment. Why is this the case? What are the social pillars behind this pioneering program that feed into social mobilization around patents? The first case of AIDS was diagnosed in São Paulo in 1983, and two years later the central government established a National AIDS Program. Despite popular perceptions of Brazilian sexual promiscuity, AIDS policies during the 1980s were not unlike those of other countries in that responses were built around denial and stigma (Biehl 2007). Brazil's leaders did not consider the disease to be a priority amidst a crumbling public health infrastructure. AIDS was considered a problem for the rich, internationally-connected gay community (Cristiana Bastos 1999).

Brazil's democratic transition during the 1980s was also a time rich with discussions of citizenship and the development of civic associations interested in redefining state-society relationships. In the view of Dr. Marco Antonio Vitoria (2006),

one of the developers of Brazil's AIDS program, if AIDS had not struck Brazil during the democratic transition, the country's history would have developed differently. That is, the democratic opening provided a gateway for a new group of actors who were inspired by the ideal of universal public health as a form of social justice as these sanitaristas entered public administration. They tended to have a statist approach towards universal health care but wanted to move away from corporatist practices of the past and encourage public engagement based around ideas of citizenship.

The sanitary reform movement failed to achieve its objectives, except in addressing HIV/AIDS. Unlike other areas of the public health establishment that did not have a mobilized constituency, the spread of AIDS inspired a social movement that pressured for public policies (Nunn 2007; Paulo Teixeira et al. 2003; Passarelli and Júnior 2003). The sanitaristas finally had a political ally to help them press for reforms. In the words of former president Fernando Henrique Cardoso, the "state and the social movement practically fused" (quoted in Biehl 2004: 114).

The alliance between "social movement insiders" and grassroots organizations began at the municipal level (Biehl 2007). With the central government unconcerned about the disease, AIDS patients sought out municipal health centers to obtain information and treatment. These local health facilities were typically staffed by sanitaristas who were gaining experience in dealing with stigmatized diseases such as leprosy.

The social origins of the AIDS groups must also be highlighted. The disease first spread amongst an urban, middle class stratum of society capable of mobilizing resources to establish social movement organizations. The case of Herbert de Souza, a famous sociologist who returned from exile in 1980s and had contracted HIV through a blood transfusion, best illustrates this renewed democratic activism. Based on his foreign

contacts and fundraising skills, he created a number of organizations to provide care and treatment as well as advocacy, including the Brazilian Interdisciplinary AIDS Association (Associação Brasileira Interdisciplinar de AIDS—ABIA). During this time, civil society organizations addressing the AIDS crisis also sprung up in other urban centers throughout the country.

Scaling up Brazil's AIDS program to the national level was facilitated by World Bank money. By the early 1990s, the World Bank was investing heavily in international health care, often times backed by a strong neoliberal ideology (cf. Homedes and Ugalde 2005). But due to criticism of their environmental policies in the 1980s, Bank officials began to demand more social participation in the loan projects (Rich 2009).

In the case of Brazil, the World Bank was predicting that the number of AIDS cases in the country would reach one million by 2000 if strong action were not taken. After reactionary AIDS policies developed during the administration of Fernando Collor (1990-1991), new progressive leadership assumed command at the National AIDS Program and signed a $250 million loan agreement ($160 million from the World Bank and $90 million from the Brazilian government) in 1993 to establish prevention and control activities. Technical personnel from the bank involved in the loan agreement did not push a neoliberal stance but instead shared many of the views of their Brazilian counterparts (Biehl 2007). Disputes on the two sides remained, as in the case of Bank officials' preference for prevention programs as opposed to treatment provision (Mattos, Júnior, and Parker 2003). Nonetheless, the World Bank loaned an additional $300 million in 1998 for expanding treatment and prevention programs.

World Bank loans had a major impact on state-society relations. Contrary to the trend of the outsourcing of services and competition with NGOs (Roberts 2005), the Brazilian state centralized AIDS policy-making and established clear lines of action

between the state and civil society organizations that received World Bank disbursements. The national AIDS program focused on treatment and national prevention strategies, especially the use of the media, while NGOs worked at the community level and with stigmatized groups.[22]

World Bank money did more than just provide the basis for good governance—it transformed the National AIDS Program into a political force. The inflow of funding allowed the National AIDS Program to pay higher salaries to qualified professionals working at NGOs (Nunn 2007). Activists who established powerful social movement organizations now had the opportunity to assume positions of power within the government. "Activists gave up their antagonism toward the state and organized, together with politicians, social scientists, and public health professionals, an impressive apparatus of HIV/AIDS control" (Biehl 2007:65-66). Indeed, now these AIDS bureaucrats began mobilizing grassroots organizations, often times for explicit political campaigns at the national and sub-national level (Rich 2009).

The coalition between the sanitaristas and grassroots AIDS activists was strengthened and renewed in each political confrontation, with each outcome resulting in the expansion of collective rights. The coalition fought to reform dangerous blood bank practices, extend disability and pension status to people with AIDS, and defeat a bill to restrict the entrance of HIV-people into the country (Biehl 2007). Some of these victories occurred in the 1980s before World Bank funding began, but they are indicative of the growing ties between grassroots organizations and "social movement insiders." When access to medicines became an issue, this dual alliance had already achieved a formidable track-record in ensuring collective rights.

[22] Brazil's AIDS policies resembles Tendler's (1997) accounts of good governance, but at the federal level.

Pharmaceutical Citizenship for AIDS Patients

The biggest accomplishment of insider and outsider activists was the passage of Law #9.313 of 1996, otherwise known as Sarney's Law, after the bill's sponsor, Senator Jose Sarney. The law declares that everyone living with HIV or sick with AIDS will receive, for free, all the medication and treatment that is necessary through SUS. The law goes beyond Brazil's constitution, which mandates that the state will guarantee access to health, yet does not obligate the government to provide all treatments for free. Sarney's Law represents powerful legislation obliging the state to incur the costs of acquisition and distribution of the life-saving anti-retroviral medicines (ARVs)

Free and universal distribution of medicines to treat opportunistic infections and HIV/AIDS began in the health secretariat of Sao Paulo in the early 1990s. The new law replicated this policy at the federal level and came soon after the discovery of triple-therapy in fighting AIDS. Monotherapy had proved unsuccessful in treating the disease, but use of up to three different drugs attacking points of virus replication changed AIDS from a death sentence to a chronic disease.

Sarney's Law states that the Ministry of Health will standardize treatment protocols—that is, establish guidelines for when patients should begin treatment and determine which medicines will be used as first, second, and third-line treatments. Consequently, an advisory group to the National AIDS Programme (NAP) meets annually to review scientific findings concerning current and new anti-retroviral medicines. Their conclusions comprise the therapeutic consensus, or the specific guidelines physicians are encouraged to use when prescribing medications. [23]

[23] Appendix 2 lists ARVs according to their drug classification and provides the date they were included in the therapeutic consensus.

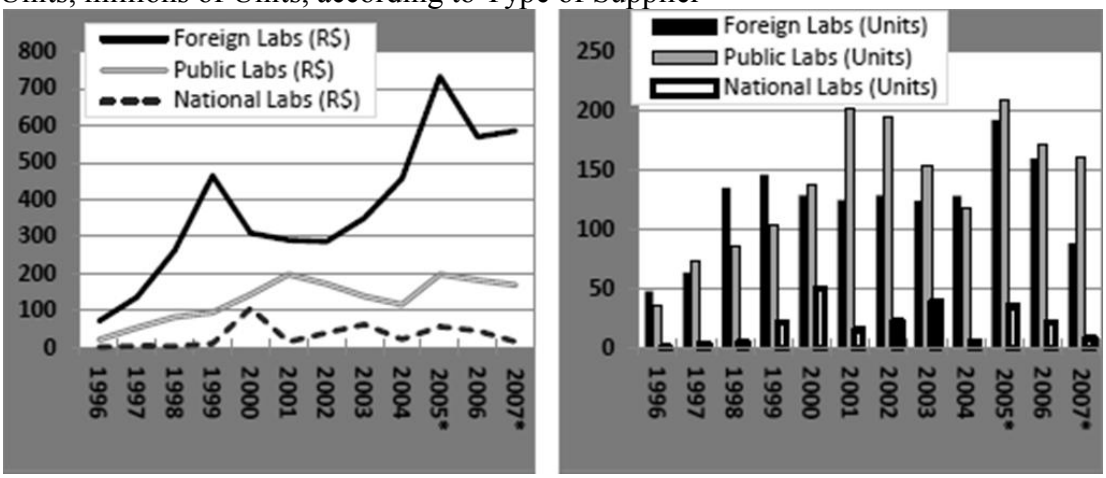
If patients adhere to the treatment protocols, they can keep the virus in check and, although they are never cured, they can live healthy lives for many years. Treatment fails when protocols are not followed or when the virus develops resistance to medication. Patients must then take second and third-line therapies. Through time, some therapies become more common because they exhibit fewer side effects and/or more potency compared to others. Efavirenz, for example, was initially denoted as a second-line therapy, but due to ease of use and potency, many physicians began prescribing it as a first-line therapy. While the therapeutic consensus provides guidelines, doctors remain sovereign in prescribing which medicines their patients will use.

The biggest threat to the AIDS program after Sarney's Law was passed in 1996 was securing government financing. Brazil has a notorious history of passing progressive legislation without the means or political will to transform the law into reality. With protests, court orders, and constant pressures, Brazil's AIDS coalition ensured there were enough fiscal resources to purchase medicines. Even the country's 1999 monetary crisis and ensuing fiscal austerity did not affect AIDS budgets. Ministers of Health who did not address the concerns of this powerful constituency saw their political careers cut short, while others who trumpeted AIDS increased their political capital (Nunn 2007). The seeds of Brazil's reputation dividends were beginning to sprout.

Acquisitions of ARVs by the Ministry of Health occur on a yearly basis (unless emergency purchases need to be made) and must follow strict procurement guidelines. Public procurement made by all sectors of the Brazilian government, including the Ministry of Health and public labs, is governed by Federal Law 8.666, or Law of Tenders. Approved after a corruption scandal involving Brazil's first elected president after the military dictatorship, Fernando Collor, the law was passed by Congress in 1993 to re-establish credibility in government purchases. The guidelines set forth in the law

have led to an increase in bureaucratic procedures while establishing as a reference the lowest price for purchases without consideration of national production or other criteria. The law remains an important obstacle when attempting to use the purchasing power of the state to develop the domestic pharmaceutical industry, especially with regard to the local production of ARVs (Marques and Hasenclever 2008).[24]

Graph 2: ARV Acquisitions by Expenditures, millions of reais (R$), and by Number of Units, millions of Units, according to Type of Supplier



Source: Flynn (2008)
∗ Refers to years in which purchases were also made via international governmental organizations, not included in the graphs but accounting for 9–10% in terms of volume.

Graph 2 shows purchases of ARVs expenditures and units according to the type of supplier. While payments to private national labs remained marginal, foreign labs have increased their revenues as the program has progressed, and amounts paid to public labs increased in the first five years before leveling off. Foreign and public labs provided the bulk of medicines, while national, private drug makers contributed limited amounts. Most strikingly, Brazil reduced payments to foreign firms after 1998 as they substituted

[24] Chapter 4 addresses the challenges posed by Law 8.666 to the development of local ARV capacity.

imports with local production. With patent protection on new second-generation medicines, however, transnational drugs firms have been able to increase their revenues from 2003 onward.

CHAPTER SUMMARY

Neoliberalism tends to be depicted as the strength of global capital to force developing countries to open their markets to global trade and finance (McMichael 2004). This chapter argues that the dissolution of the development alliance resulted in the increasing distance between the state and transnational corporations (TNCs). With open markets and patent laws, transnational drug companies no longer required state support, but neoliberalism combined with democracy brought new actors into the state arena. Those groups that were best mobilized and developed the strongest partnerships with activist bureaucrats were able to advance their citizenship claims. The formidable coalition that developed to fight AIDS represents the exception to the rest of Brazil's public health care system.

In the next chapter, I detail the origins of Brazil's local production of pharmaceuticals and the state's decision to produce them in public (state-run) labs. The period marks the high point of state autonomy and reduced external dependency. The assertion of patent power by foreign drug companies, however, would challenge the sustainability of Brazil's free and universal access program. Brazil's dual alliance of AIDS activists responded by pushing the "reputational dividends" of its successful AIDS program.

CHAPTER THREE – ESTABLISHING LOCAL PRODUCTION OF AIDS MEDICINES AND EXPLOITING REPUTATIONAL DIVIDENDS (1990-2001)

The best industrial policy is no industrial policy.

--Pedro Malan, Brazil's Minister of Finance 1995-2002

This chapter describes the evolution of Brazil's technological capabilities to produce the first generation of anti-retrovirals (ARVs)[25]. Brazilian firms, both private and public, reverse-engineered these medicines, thereby broking the monopoly power of transnational drug firms. After the passage of Sarney's Law in 1996, which mandated free and universal distribution of ARVs, policy makers decided to mobilize state resources to produce ARVs for Brazil's national treatment program. The expansion of state capabilities would have long-term, unforeseen consequences for the development of the country's pharmaceutical base and varying capabilities to reverse-engineer medicines, especially the second generation of ARVs protected by patent. That patent laws were not in place provided the policy space for a quick response to the AIDS crisis, whereby the country could pursue autonomous development and avoid dependency.

Despite the strong ties between social movements and Brazil's National AIDS Program, pharmaceutical policies related to AIDS medicines in the late 1990s were driven by state authorities. The World Trade Organization (WTO) panel the United States brought against Brazil concerning aspects in its intellectual property laws created a political opportunity that not only crystallized alliances between the Brazilian state and national activists but also created the necessary conditions to scale up the pro-AIDS

[25] See Appendix Three for a list of ARVs used in Brazil's program. First generation ARVs refer to those without patent protection: zidovudine, didanosine, zalcitabine, stavudine, lamivudine, nevirapine, delavirdine, saquinavir, ritonavir, indinavir and fixed-dose combination lamivudine + zidovudine.

coalition to the global level. By exploiting the "reputational dividends" of their banner AIDS program, Brazilian health officials mobilized their base and reached out to transnational advocacy groups under a common frame: "Access to life-saving medicines is a human right." Human rights groups supported Brazil's threat to use a compulsory license when negotiating prices with patent holders, but in the end, it was Brazil's ability to produce patented medicines that convinced foreign drug companies to reduce their prices to levels demanded by Brazil. With the price discounts, Brazil backed off the compulsory license.

"BRAZILIAN AZT": THE STORY OF MICROBIOLOGICA

The first medication found to have an effect on HIV/AIDS was the anti-retroviral medication zidovidine (AZT), discovered by researchers at the National Cancer Institute in 1985 and licensed to UK-based Burroughs Wellcome (now GlaxoSmithKline—GSK). In the face of the growing AIDS epidemic, the Secretary of Health of São Paulo state was the first government agency to begin the free distribution of AZT in 1989. The federal government's National AIDS Programme (NAP) as well as a number of large companies followed São Paulo's lead and also began to purchase the drug in the early 1990s. The sole supplier at the time was Burroughs Wellcome, which won all the contracts until a new Brazilian start-up company, Microbiologica (MB), began producing the drug. The transnational drug company's market control, not only in Brazil but worldwide, was threatened by the start-up.

Jaime Rabi, a Chilean-born chemist trained in the United States who played a key role in developing "Brazilian AZT", recounts MB's trajectory in the academic journal

Quimica Nova (Rabi 2007).[26] The company began as an offshoot of the Federal University of Rio de Janeiro in 1981. Contrary to Brazilian academic culture, professors from the Department of Chemistry decided to enter the world of business. MB first produced cultures and reagents for the diagnosis of tropical diseases, but responding to a government initiative for the national production of strategic medicines and active principals, decided to enter the line of chemical synthesis. With funding from the federal Central Medicines Agency (CEME), MB established a chemical division and brought in Rabi, a UFRJ professor, as a consultant. By the end of the 1990s, the lab had established its credibility and competence in the production of nucleoside-based compounds, such as mercaptopurine and azathioprine.

Due to their small scale and exploitation of niche markets, MB survived the market liberalization of the early 1990s while many other manufacturers of fine chemicals filed for bankruptcy. Lelio Maçiara, a chemical engineer and former student of Rabi, who joined MB to assist his former supervisor, said that "MB never risked much, to do large investments, and never had loans. Thus when the neoliberal wave hit, we were not a risk because we were not in debt" (Maçiara 2007). The new key niche market that MB entered was the production of AZT. Rabi (2008) explained that the reasons for producing AZT were related to the highly emotional aspects of the disease as well as new business opportunities:

> When you have the opportunity to enter into a new field, you have the chance to leverage your organization and the chance to grow because of the unmet necessities which require an urgent solution. Of course, there were various factors that contributed to our being able to make AZT on an industrial scale. First, we

[26] Previous research on Microbiolgica was carried out by Amy Nunn (2007). My narrative of Microbiologica's history coincides with hers, but I also incorporate Rabi's published accounts, conflicts over dumping and the entrance of other local competitors into the market.

> had experience with nucleosides and second we already had experience in industrial chemistry. Additionally, there were no competitors in Brazil. There was only the transnational company Wellcome. We were the only local company against Wellcome. The size of Wellcome compared to us at the time made us look insignificant. Of political interest is the fact that for the first time a Brazilian company was taking advantage of the possibility to make in Brazil a new medicine which was protected by patents outside Brazil.

Two government programs supported MB's move into the production of AZT. First, the Support Program of Scientific and Technological Development (*Programa de Apoio ao Desenvolvimento Científico e Tecnológico*) allowed MB to invest in quality control and in robust synthetic processes at the laboratorial scale. Second, the Financing Agency for Studies and Projects (*Financiadora de Estudos e Projetos*—FINEP) provided financing to purchase necessary machinery and equipment. In 1992, MB officially launched "Brazilian AZT" and won its first public bid to sell 16,600 cases (equal to 100kg of AZT). MB's price was $100 per 100 tablets versus Burroughs-Wellcome's price of $140 (Abrahams 1992).

In the early 1990s, Brazil's federal treatment program was in its nascence. Although Lair Guerra, the director of the National AIDS Program, had been placing AZT orders for federal programs, MB sold to other clients, including large Brazilian companies such as the federal bank Banco do Brasil and the mining company Vale de Rio Doce, which provided medicines to their employees. Maçiara (2007) explains that MB's commercial strategy remained conservative. The company did not have a marketing department and sold all that it could produce. "We opened up an office just to sell to individuals too. Patients used to go directly to the factory to buy medicines since the product was not sold in pharmacies," explained Maçiara. Because it owned few of its installations, MB subcontracted most of the production to other companies, including the

production of finished dosage forms. In hindsight, Maçiara explained the business mentality of the company:

> We thought small, always very conservative. We never invested what we needed to in order to attend the whole market. We only sold that amount which we could produce. We only invested in those areas in which payments were already made. It was a very conservative vision. We had something very important in our hands; only we knew how to do it. We should have done the investment that was necessary, to do a world-scale plant, so that the whole world could become a consumer of our products.

Risk averse, the owners of MB missed an opportunity to increase the scale of its activities. But the company also operated in an environment with minimum government support during the 1990s and in a market dominated by incumbent pharmaceutical firms.

Competitors were quick to respond to MB's entrance into the market. When MB first synthesized AZT in the early 1990s, it was one of the few producers in the world besides the patent holder (Burroughs Wellcome) to offer the product. MB's production remained limited and supplied only half of the total procured by the public sector (Maçiara 2007). Nonetheless, the TNC felt its market threatened and began to lower its price in order to drive MB out of business. "The extreme dumping consisted of donations," Rabi said. This occurred not only in Brazil but also in export markets such as Chile. MB took the transnational drug company to court on charges of systemic dumping, but withdrew its case because of an inability to achieve a ruling in Brazil's notoriously slow judicial system. Another front against MB opened in the press where articles appeared that questioned the quality and safety of its products[27], but despite the

[27] Jorge Raimundo (2008), who worked for Burroughs Wellcome before it merged with GlaxoSmithKline, said the company attempted to convince federal authorities to purchase only their product by arguing that their product's quality was superior, but the government was satisfied by MB's standards

inexistence of an independent regulatory agency (ANVISA was not established until 1999), MB had already established itself as a producer of quality medicines during the 1980s.

MB was not the only Brazilian firm to enter the ARV market in the early 1990s. The year after MB launched "Brazilian AZT", another small start-up, Labogen, based in the city of Campinas, São Paulo state, produced its first batch of the active principal. After failing in the field of biotechnology related to agriculture, the company's owners decided to enter the fine chemicals industry and already had set up a factory with money provided by the Brazilian National Development Bank (*Banco Nacional do Desenvolvimento Econômico e Social*—BNDES). "We knew that AIDS was a big problem and that there will be constant demand for products. [Former President] Collor opened up the market to imports in 1990, and we knew that AIDS products were value-added items," explained the company's former director, José Machado de Campos Neto (2008). Similar to MB, the company had strong links to a local university. Labogen began as an incubator renting out an area from the Multidisciplinary Center on Chemical, Biological and Agricultural Research at the University of Campinas. It also had the support of FINEP, which provided R$ 1 million (about $1 million at the time) in funds required to reverse-engineer the API. Labogen only produced the API and established a partnership with Brazilian drug company Medley to produce the finished dosage form.

While most of the Brazilian fine chemical sector was shrinking during the 1990s due to increased international competition, a few firms survived market liberalization and demonstrated the technical ability to produce advanced active principals used in cutting-edge medicines. MB and Labogen could now reverse-engineer compounds and begin industrial production without having to respect patents. The process of "learning by doing" that began with AZT carried over into the production of other active principals

used in AIDS treatment. MB also began production of estavudine and lamivudine, and Labogen developed estavudine, didanosine, and nevirapine as well as the API for ganciclovir, a drug used for treating AIDS-related opportunistic infections. The initial successes of the two API manufacturers would change as Brazil's public (or state-owned) labs began producing ARVs.

THE DECISION TO PRODUCE ARVS IN PUBLIC LABS

First Initiatives by Public Labs

During the 1990s, Brazil's public labs operated below capacity, lacked resources to invest and modernize production, and were under the pressure of privatization. Despite their difficult financial and management problems, many labs continued to play a vital role in public health programs (cf. Cosendey et al. 2000; Egléubia A. Oliveira 2007). It should therefore come as no surprise that several public labs began to produce ARV medicines. Technicians from MB assisted public labs such as the Pharmaceutical Laboratory of Pernambuco State (*Laboratório Farmacêutico do Estado de Pernambuco*—Lafepe) in providing analytical methodology and standards for the production of finished dosage forms of AZT (Nunn 2007). Since public labs did not have capabilities with synthetic chemical processes to produce active principals, they focused on pharmaceutical formulations. When developing pharmaceutical technology for the fabrication of pills, capsules and syrups, however, they faced significant challenges in terms of human capital and equipment.

In 1994, Lafepe was the first public lab to begin production of AZT but was dependent on outside suppliers for the technology, as opposed to MB and Labogen that produced the API in-house. Before the advent of the AIDS crisis and new government investments in public labs, most of these facilities did not have in-house research and development divisions. Instead, most state sector labs relied on suppliers of active principals to provide the pharmaceutical technology required to make the finished dosage forms[28]. In-house pharmaceutical technology in formulations allows producers to better specify the inputs and raw materials they require; otherwise, they become dependent on just one supplier. After completing studies in France and gaining experience at the French drug company Sanofi-Adventis, Pedro Rolim was well-positioned to establish such a center at Lafepe.. He explained the political climate at the time he began working at Lafepe and why the lab entered into the ARV market (Rolim 2008) by stating,

> The Ministry of Health was dependent on importing ARVs. There was a big debate about the development of ARVs, so they invited the public labs to produce them. Brazil's intellectual classes were invited to participate in developing ARVs for AIDS. So the Ministry of Health, stimulated by the fact that AIDS was a disease of the rich, used the network of public labs to begin production and provided the resources. The public labs were used because they were part of the government so they would implement a policy of the government… Lafepe at the time was almost completely obsolete and did not have the capacity to develop the medicines. But Lafepe was one of the labs that was chosen and received incentives and resources to improve its infrastructure. So with those resources we were able to set up our R&D lab and develop the first ARV formulations.

In the following years, Lafepe developed in-house formulations for a pediatric version of AZT, lamivudine, estavudine, and didanosine.

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[28] Typically, this would come in the form of a Drug Master File, which usually contains confidential details about the manufacture and production of APIs and finished dosage forms. It is provided to regulatory officials in order to register a medicine for commercial distribution.

By the time Sarney's Law mandating free and universal distribution of AIDS medicines was passed in 1996, several public labs controlled by state governments were in a position to contribute to the program. According to Ministry of Health (2008a) data, in the first two years after Sarney's law passed, Lafepe provided up to R$ 72 million worth of zidovudine (both capsules and oral solutions) and staduvidine, but foreign firms continued to dominate ARV sales to the government, totaling R$ 200 million, whereas sales from national firms such as MB and Labogen reached only R$ 5 million.

Data from the Ministry of Health (2008a) suggests that public labs were competitive in terms of pricing. News reports say that Lafepe was selling a box of 100 capsules of AZT for R$ 54-56 compared to private sector's price of R$ 97-120 (Junior 1997; Lins and de Paula 1996). Without access to the bids made to supply the medicines, generalizations cannot be drawn, but direct comparisons show that local production was cheaper than imports. In the case of zalcitabine, the Ministry made two purchases in 1997: one from the foreign lab at R$ 1.70/pill and one from the national lab at R$ 1.17/pill, and both acquisitions were for comparable volumes of 3.2 million pills. Comparisons between local private and local public production reveal similar prices: public labs provided AZT oral solutions at R$ 9.89 per dose in 1997 compared to the national private sector's price of R$ 10.29 per dose in 1996.[29]

[29] A few caveats are necessary when comparing costs between public and private labs. Public labs do not have to pay taxes, import duties on raw materials, dividends to shareholders, or overhead on marketing and advertisement. In addition, most employee salaries in public labs come from public sector budget outlays. However, since most labs operate under rules and regulations governing the public sector, they cannot raise their own capital nor have working capital in order to make purchases of inputs required for production. Typically, the state government would have to provide the resources required to purchase APIs and other raw materials. For the federal lab Farmanguinhos, the Ministry of Health would forward the money necessary to purchase medicines. Private labs are more efficient in terms of hiring and firing personnel as well as establishing supply contracts, but they must pay taxes that can account for up to one-third of their sales as well as generate profits for their owners and high payouts to executives.

Federal Government Begins ARV Production

Although Lafepe and a few other public labs had already launched production of a few medicines, the Ministry of Health turned to its in-house facility, Farmanguinhos Institute in Medicines Technology (*Farmanguinhos Instituto de Tecnologia em Fármacos*—FM), to be the main supplier. During the 1990s, the lab was being restructured under the leadership of Eloan Pinheiro.[30] She recounts how FM became involved in producing medicines during meetings with Pedro Chequer, director of the National AIDS Program, and the Minister of Health, Carlos Albuquerque:

> They considered back then, and continue until this day, that FM should be the leading lab. They decided at the time that FM would be with 40% of the demand for ARVs, 30% from public labs, and 30% from private labs. This meeting occurred in the Ministry of Health at the beginning of the program. They wanted to give 100% to FM. But told [her ministry officials] if you just have one then you would have none. You don't want to have a monopoly. You could have a problem, a machine breaks done, and then there would be delays and who would be penalized? The patient. Second, FM is a regulatory body for the Ministry of Health. This means that FM would make its cost available and make all the prices it pays transparent because you can't interfere in the other state labs but in FM you can. FM is not under contract, but the other labs are. FM makes a direct agreement with the Ministry of Health. For those products that FM developed itself, it could transfer the technology to other labs.

[30] The biography of Pinheiro is interesting. She worked for UK drug maker Beecham, but remained involved in Brazilian leftist politics including the re-democratiziation process and was a leader of the chemical workers' union of Rio de Janeiro, as well as in efforts to reform the public health system. After her tenure at the drug maker, she became a consultant to Brazil's public labs until her election as the director of FM in 1994. Under her leadership when she left in 2002, the lab had increased its product line from three products to sixty-four.

The federal lab collaborated the most with the São Paulo state lab (*Fundação para o Remédio Popular* – FURP) due the latter's capacity and adoption of Good Manufacturing Practices (GMP) for drug production.

The process of depending on public labs for producing ARVs developed gradually, but the initiative began relatively early in the institutionalization of Brazil's program of universal access. From the perspective of the managers of public labs interviewed for this thesis, a consensus emerged as to how these state enterprises came to play an important role (Pinheiro 2008; Oliva 2007; Pereira Gomes 2008; Rolim 2008). First, the AIDS program was directed by the federal government, and past public health initiatives depended on inputs supplied by public labs. At the time, several public labs were operating below productive capacity. Second, Brazil was dependent on imported ARVs to supply the program so there was an interest in nationalizing the production of these vital medicines in order to reduce costs. Without a national private sector having developed the entire spectrum of medicines, the government turned to public labs and provided the necessary resources to improve their operations. Third, the role of public labs is to train people in pharmaceutical production. In the advent of the AIDS crisis, Brazilian society had called upon the country's leading scientists and professionals to support the program. Most public labs had ties to public universities to draw on additional human capital and contribute to graduate level educational programs.

One last reason why the government relied on public labs is a certain level of distrust of the private sector. The view of those working on pharmaceutical policies at the Ministry of Health and the directors of public labs is that the private sector is solely interested in making profits and not supportive of public health objectives. Pedro Chequer (2008), former director of NAP (1996-2000; 2004-2005), best articulated this vision:

> There is an ideological aspect related to the role of the State in the economy despite the new winds of neoliberalism and globalization. Besides being a regulator of the market and promoter of public policies, the State should also be the provider of goods and inputs. Obviously in a capitalist system, the state cannot be the provider of everything. But in some areas the State should not just be a policymaker or leader, but participate directly in certain areas such as education and housing...In the area of health, the Constitution is clear that health is a right of citizens and duty of the State. In this aspect, the Constitution does not restrict the State to just the provision of services but also includes the provision of goods and inputs…In concrete and operational terms, the State guarantees sustainability of the program. The State is not subject to variations in the market. The question that is important is the outcome of a permanent policy. In the case of AIDS, one of the prerequisites and successes of the medicines policies is the permanent provision of medicines on a routine basis and without interruption. We cannot be subject to a factory being sold or the closing down a line of production or simply believing that the price should be different…

Chequer, a *sanitarista* and vocal proponent of communist tendencies, represents the most statist approach to medicine policies, which other *sanitaristas* do not share the view on the state's role.

The political climate at the end of the 1990s contributed to policy makers' distrust in the private sector. As chapter two recounted, there were numerous scandals involving falsified products and exorbitant price hikes. The business strategies of MB and Labogen should not be discounted in the government's decision to monopolize the first generation of ARVs. Brazil's pharmaceutical sector had and continues to have more companies that focus on the last stage of production—formulation and marketing—but only a few API manufacturers could position themselves to control the market. Neto (2008), the former director of Labogen, explains the company's strategy during the 1990s:

> Many private national labs are registered to produce ARVs, such as Cristalia, Eurofarma, etc. We saw that there was a market opportunity—we could control the market, and that it was much easier for two companies, Labogen and Microbiologica, to sell to the government than to a pulverized private market. Labogen and Microbiologica ended up establishing a policy together to sell to the official labs. We established an informal agreement to divide the market between the two of us. Labogen would do estavudine and MB would do lamivudine, for example, in which each could develop economies of scale.

Labogen and MB's ambitions to the control the market had unforeseen consequences when public labs decided to import raw materials, and their strategy contributed to public officials' distrust in the private sector. Pinheiro also said that partnership was not established with MB because the company was interested in monopolizing AZT (see Flynn 2008).

Since the start of Brazil's universal treatment program for AIDS patients, the government was interested in maintaining control of production in the public sector. The irony in Brazil's case is that the country had been implementing several neoliberal reforms during the 1990s, especially privatization. Indeed, elected officials in Pernambuco state were also lobbying for the privatization of Lafepe but changed course with the increased sale of AIDS medicines and investments from the federal government. The arrival of a new minister of health in 1998 was crucial to this policy reversal.[31]

Jose Serra Assumes the Ministry of Health and Scales Up ARV Production

The evolution of Brazil's public production of ARVs is closely tied to the political trajectory of José Serra. Exiled from Brazil during the military dictatorship,

[31] For a full discussion concerning the policy reversal of Lafepe's privatization see Andrade de Oliveira (2007).

Serra returned to Brazil and helped found the Brazilian Social Democratic Party (*Partido Social Democratico Brasiliero*—PSDB) together with Fernando Henrique Cardoso (FHC). Serra, before assuming command at the Ministry of Health, was the Minister of Planning (1994-1997). He had definite political ambitions and would become the PSDB's candidate for president, to succeed FHC's two terms in office (1994-2002).

Everyone interviewed during this thesis acknowledged that Serra had presidential ambitions and used his stay at the Ministry of Health from March 1998 to February 2002 for public promotion. Interviewees also said that Serra was one of the most powerful and capable Ministers of Health in recent Brazilian history. With the personal support of the president and a strong following in Congress, Serra capitalized on the country's problems related to pharmaceuticals and pushed through significant legislation affecting the sector, such as the Generics Law and creation of ANVISA. He also played a lead role in exploiting the "reputational dividends" not only for his personal political ambitions but in international venues. Lastly, it is worth mentioning that Serra represented the faction of the PSDB interested in using state power to promote national development, even though the party under FHC had enacted several neoliberal reforms reducing the government's role in directing the economy.[32]

When Serra assumed control of the Ministry of Health, Brazil had already passed legislation mandating free and universal distribution of AIDS medicines and a new bill protecting patents on pharmaceuticals. The challenge was to scale up production as quickly and effectively as possible. Serra rose to the challenge. In 1997, the year before coming to the Ministry of Health, Brazil had 35,900 patients receiving ARVs and by 2002, the number increased to 119,300. Serra also had to manage the Ministry of Health

[32] FHC, a famous sociologist who contributed to dependency theory and had advocated the use of state policies to overcome dependency, said in 1993: "Forget everything I wrote. The world has changed."

during an economic crisis and budget cuts. In January 1999, the country was forced to devalue its monetary unit, the real, which had been anchored to the dollar in order to fight inflation. Despite budget constraints, expenditures on ARVs increased from R$ 191 million in 1997 to R$ 496 million in 2002 when Serra left office. Reducing annual per patient costs on ARVs was the key to success, falling from R$ 6,223 in 1998 to R$ 4,158 in 2002 (Grangeiro et al. 2006). He achieved these outcomes through the local production of ARVs and aggressive negotiations with foreign drug companies.

Serra was not the sole actor responsible for the success of the AIDS program. He also counted on the support of committed social servants and mobilized civil society. The alliances between government and civil society has been amply documented (Nunn 2007; Parker 1997; Chequer 2005; Cristiana Bastos 1999; Paulo Teixeira 2003; Paulo Teixeira et al. 2003; Passarelli and Júnior 2003). One common theme in this literature is the constant mobilization by civil society and personnel in the National AIDS Program for securing treatment funding. Although Sarney's Law was on the books, lobbying by Pedro Chequer, the director of the NAP, and protests from the AIDS community as well as continued judicial actions were crucial in the face of economic crisis and fiscal restraint. Health officials and social movements cemented their already strong ties, while Serra was the head of the Ministry of Health.

To organize the public production of medicines, the Ministry of Health selected those labs that were in the best position to develop ARVs and had sufficient productive capacity. The Ministry of Health could chose from the 18 public labs located throughout the country.[33] Appendix Two lists the public labs registered to produce ARVs. The allocation of production during Serra's time at the Ministry of Health favored FM.

[33] For more information on Brazil's public labs see: (Flynn 2008; Egléubia Andrade de Oliveira et al. 2006)

Between 1998 and 2001, ARV purchases from public labs other than FM hovered between R$ 39 million and R$ 54 million while FM increased sales from R$ 0 in 1997 to R$ 143 million in 2001. The inflow of resources allowed FM to expand its research and development and even provide extra resources to the FioCruz medical complex where it is housed. During these years, FM provided reference prices for ARVs, but the Brazilian Association of Public Labs (*Associação dos Laboratórios Farmacêuticos Oficiais do Brasil*—Alfob) negotiated allocations and prices for the other public labs with the Ministry's Department of Pharmaceutical Assistance. Acquisitions from national public labs remained marginal except in 2000 when the Ministry purchased R$ 106 million worth of ARVs from this sector.

Favoring public labs at the expense of private labs went against the original plan established at the onset of the program and is ironic given Serra's term at the Ministry of Health. His administration enacted several policies favoring the domestic pharmaceutical sector, such as the Generics Act, yet marginalized private national producers of ARVs.[34] By the end of 2002, there were 19 national drug makers registered with ANVISA to sell ARVs. Only Laob, Eurofarma, Neo-Quimica and Cristalia had closed large contracts during these years (Orsi et al. 2003: see Table 3).

Farmanguinhos and other public labs were able to scale-up production because Serra provided additional resources for investments to expand capacity. The Ministry of Health's Guarda Chuva Project (Umbrella Project) provided R$ 41.3 million to the country's public labs between 2000 and 2002. The project, designed not only for ARVs but for an entire spectrum of medicines produced by the public labs, increased drug

[34] Research and conclusions in this section are limited by the fact that Jose Serra was unavailable for an interview, and Barjas Negri and Platão Fischer, second-tier level officials working at the Ministry of Health during Serra's term refused interview requests. But third-tier officials Fernando Cardenas and Carlos Alberto Pereira Gomes were interviewed.

production 368%, or from 1.89 billion to 8.87 billion units. Some interviewees from public labs who did not receive resources claim that the investments were tied to political objectives. Since Serra was running for presidency, these informants claimed, he did not want any of the Ministry of Health's resources to benefit labs of state governments governed by opposition parties. Other state labs controlled by allied political parties, for example Lafepe, reversed plans for privatization after receiving purchasing contracts and investments from the Ministry of Health (Egléubia A. Oliveira 2007). Fernando Cardenas (2008), who was in charge of *Guarda Chuva* at the Ministry, denies that there was any political bargaining and states that the investments were based on technical criteria.[35]

While the main objective of the government was to reduce overall expenses of the program, the strategy was to increase local production of ARVs in order to reduce payments to foreign companies. However, the largest outlays continued with payments to foreign pharmaceutical companies. This resulted from the inclusion of new second-generation ARVs, such as protease inhibitors, that were protected by patent. Pinheiro (2008) said the government's plan was first to develop all the off-patent medicines and then begin work on patented ARVs used in the program.

Developing ARVs and Sourcing Raw Materials

Due to previous government programs and efforts to stimulate a national drug industry in the 1970s and 1980s, Brazil had trained scientists and engineers capable of reverse engineering chemical compounds and developing new synthetic processes and drug formulations. MB followed by Labogen spearheaded initial domestic efforts to

[35] The data collected for this dissertation does not provide conclusive evidence regarding the political use of these investments but the possibility, given the nature of Brazilian politics, cannot be discarded.

develop ARV drugs. MB also shared its accumulated knowledge of drug development with Brazil's public labs, such as passing on analytic standards (Rabi 2008; Nunn 2007). Partnerships between private and public companies, such as in the case of Labogen and Lafepe, also resulted in the development of new medications for AIDS patients (Neto 2008; Rolim 2008). Despite these initial contacts across the public-private divide, public labs ended up turning towards foreign suppliers for sourcing their raw materials, and Brazil's domestic API manufacturing industry became marginalized. The question is why did this occur? The consequence of favoring foreign suppliers would later prove to be the Achilles' heel of Brazil's efforts to produce medicines locally and issue compulsory licenses. To answer this question, it is necessary to look at how public labs organized their research and development.

Cassier and Correa (2007, 2003) review the structure set up by Pinheiro at Farmanguinhos to develop new ARVs. Procedures were established to reverse engineer the composition of the finished dosage medicines as well as the synthetic process for obtaining the API. First, FM set up an analytic chemistry department for analyzing the quality of raw materials. The department tests raw materials to determine whether it is the same as that purported by the supplier and compares the acquired active principals to proprietary drugs. Developing in-house quality control standards and methods has allowed FM to determine criteria for purity and type of raw material. Second, FM formed a team of chemists who reverse engineer the formulation in order to identify the excipients used. Understanding which formulation works best based on bioequivalence tests allows the lab's chemists to determine which raw material they want as well as the synthetic process used for obtaining it. Lastly, based on reverse engineering techniques, FM developed purity standards and molecule references that could be added to the

Brazilian pharmacopoeia[36]. All the information necessary for producing the ARVs was not available in patents and pharmacopoeias, so the rediscovery of the qualitative and quantitative composition of ARVs resulted in a definitive learning process that could be shared with other public labs and private-sector suppliers (Cassier and Marilena Correa 2003).

The story of the development of the protease inhibitor indinavir, marketed by US-based Merck Sharpe & Dohme (Merck) under the brand name Crixivan, is emblematic of the partnerships established and challenges faced when Brazil reverse engineered medicines. The FDA approved indinavir in 1996, and it quickly became the standard for ARV therapy. Brazil's AIDS Program began to distribute it in 1997, and by the end of 2000 when FM began production, over 19,000 patients were using the protease inhibitor. The federal lab responded to the Ministry of Health's request to produce indinavir and established a partnership with Indian companies Hetero and Aurobindo—the two largest API producers at the time who were gradually moving into the ARV market. At the time, only Merck produced the API and had a worldwide patent on the product[37]. Hetero provided the first batches of the raw material, which FM formulated into medicines. Nubia Boechat (2008), FM's director research and development at the time, explained Merck's reaction:

> In the first lot that we produced of indinavir as a medicine, Merck knew that there was an element of contamination undetectable by traditional methods of quality control. Merck got a hold of a batch, did its analysis, and published its findings in the media. It caused quite an uproar, especially with all the AIDS NGOs. Merck

[36] The references provided in pharmacopoeias contain the directions for the preparation of medicines and are accessible to any generic drug manufacturer interested in reproducing a drug.

[37] Merck's patent was not applicable to countries like India and China that had not incorporated TRIPS legislation, and Brazil would deny Merck's indinavir patent request in 2003.

> knew that the product would be contaminated. They just wanted to discredit our production.

Merck had not published the existence of the contaminant in its patents for indinavir. FM called in Rio de Janeiro-based API maker Nortec Química[38] to work with a team of technicians from FM and Hetero to correct the problem. After several tests, the research team discovered that the reaction to produce the compound had to be achieved through re-cooling at a very low temperature. FM then scaled-up production and the price dropped from $1.89/capsule in 1999 to $0.47 in 2001.

The episode illustrates the close working relationships with Indian raw material suppliers and the strategy by patent holders to question the quality of medicines produced by public labs when their products are copied. Domestic API producers, such as Nortec, were not necessarily marginalized but were only contracted to work on specific programs. Besides Nortec, FM sought out another domestic API maker, São Paulo-based Cristalia, to assist in the development and supply of ritonavir.

The main problem faced by Brazil when scaling up ARV production was the lack of an extensive fine chemical sector. Neoliberal reforms and abrupt market opening forced 1,700 production lines of synthetic intermediates and inputs to shut down during the 1990s (Orsi et al. 2003). In the case of new medicines like ARVs, there were few suppliers worldwide producing the raw materials, much less all the different APIs required for the spectrum of medicines offered in the AIDS cocktail. Indeed, the first raw material FM acquired to produce didanosine was purchased neither in Brazil nor in India

[38] Nortec began as a partnership between Farmanguinhos/FioCruz and the private petrochemical holding company Norquisa in the early 1980s to produce APIs for the federal lab. The company, whose shareholders include the federal development bank BNDES, maintains an accord with FM to help develop and supply APIs. Nortec survived the sector's market liberalization since it was not accustomed to policies of import substitution and developed a competitive product profile that included exports (Soalheiro 2008).

but in Germany (Pinheiro 2008). Consequently, one important factor for why public labs became dependent on foreign suppliers was the weak fine chemicals sector.

Another reason why domestic suppliers of raw materials were overlooked is due to the specifications of the type of raw material required to fabricate certain medicines. Since FM had developed in-house pharmaceutical technology, its chemists had specific criteria for inputs used in its production (Cassier and Marilena Correa 2003). FM used rigid specifications when procuring raw material in order to insure quality, explains Pinheiro (2008). Up until the establishment of ANVISA, Brazil had a weak regulatory structure to guarantee the quality of medicines since there were no bioequivalence tests. Pinheiro explains:

> I had to do extra-rigid specifications. Many times, even FioCruz's lawyers thought that I was inducing specific suppliers and privileging them over others. So much so that Microbiologica accused me of favoring an international company in the case of didosanine because of the way I drew up the tenders. But I had done all the development with certain specifications of a type of material, the characteristics of the polymorphs of this material, which were not the same as those of MB. I remember that Jaime Rabi was very furious with me. You have the formulation, but you are not going to move your formula, redo all the tests, solubility, etc.

Having developed in-house formulations of ARVs provided public labs with the technological autonomy to choose their own supplier instead of being dependent on just one. But independence in one area resulted in a new constraint—Brazil's rigorous tender laws.

Chapter Two reviewed Brazil's Public Procurement Act (Law 8.666) which establishes the rules all public sector entities must follow when purchasing inputs. The legislation, designed to reduce government corruption, has had significant impact on

upstream ARV production (Felipe Marques and Hasenclever 2006). The procurement policy combined with the government's interest in economizing resources during fiscal constraints were crucial in the decision of public labs to obtain raw materials from abroad instead of developing local API capacity. Labogen, which only completed the final and most crucial steps in the synthesis process for making APIs, also obtained bulk intermediates from Asian suppliers. Neto (2008) from Labogen explains the situation:

> In terms of international tender, it was Jose Serra that began to carry them out in order to reduce costs. On the supply side, India and China began to know the Brazilian market because it was already selling intermediates to us and others. They knew of Brazil's market potential in ARVs. Labogen bought from South Korea, China and India which received a lot of support from their governments. When they knew they could enter the Brazilian market, they increased the price of intermediates that they sold to us and began to sell AZT and other products much cheaper.

Brazilian API producers had neither the economies of scale nor the government support required to compete against Asian producers.

Contextual factors such as fiscal restraint and the need to scale up production of ARVs as quickly as possible are part of the reason why public labs decided to import raw material instead of developing local industry. But the question remains: why were there not more partnerships established between public labs and private suppliers when developing compatible formulations and APIs? In the social circles involved in ARV production, directors, scientists, and engineers all know each other, but ultimately the government failed to establish trust across the public-private divide. Many interviewees for this research said that public-private partnerships were not common until recently and that an industrial policy was not in place to foment local development. Representatives

from the pharmochemical sector explained that they could easily reverse-engineer any ARV; they just need purchase guarantees.[39]

While Jose Serra was using state power in the Ministry of Health to promote local production of medicines, economic policy-making remained in the hands of Pedro Malan at Brazil's Finance Ministry. Brazil's economic team remained tied to a neoliberal view and worked towards dismantling the developmental state that had been in place for decades. The lack of a coordinated industrial policy became most apparent when Microbiologica opened up a factory in 1997 to produce 25t of zidovudine a year—enough to supply 10% of world demand at the time. Despite receiving support from the government financing arm FINEP to set up the facility, the lack of coordinated public-sector initiatives and Serra's decision to obtain raw material from abroad forced MB to close the plant and exit the AZT market entirely in 2000.

Even before patents became a problem, Brazil began to feel pressure from market power. Lacking a coherent industrial policy to compete against the rising pharmaceutical powers of India and China, the country was slowly becoming more dependent on the importation of key components of ARVs. More significantly, an important ally in the domestic bourgeoisie was not being cultivated.

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[39] "Private-Public Partnerships were never considered in the 1990s. In this time, policies were completely different. PPPs were considered a type of corruption. We tried often to do this and many times offered assistance in the development of new and innovating medicines for treating AIDS, for example fixed-dose combinations of lamivudine, estavudine and AZT before they existed officially. But the Brazilian government through Farmanguinhos never accepted these products because they did not exist yet on the international market. They were not interested in innovative work. They wanted to copy what already existed on the market. This was an opportunity in which public labs could have established a very strong partnership with the few Brazilian producers that existed, such as MB. But in truth, there was not an environment for this because the government just thought about the lowest price," explained MB's Jaime Rabi (2008).

SERRA'S NEGOTIATIONS WITH MERCK AND ROCHE

The success of Brazil's AIDS program began to receive worldwide attention by the turn of the century. At the Durban AIDS Conference in 2000, Brazilian officials presented data on falling mortality rates and reduced hospitalizations of people with HIV/AIDS. Between 1997 and 2000, it is estimated that 234,000 hospital admissions were avoided, representing savings of US$ 677 million (Bermudez and Maria Auxiliardora Oliveira 2004). Brazil's success demonstrated that a developing country can provide First World levels of care and galvanized efforts to replicate its success. Concerns about inadequate health infrastructures, lack of treatment adherence, and the development of an uncontrollable strain of HIV melted away in the face of Brazil's experience. The stage was set for the use of "reputational dividends" in the face of WTO and corporate pressures.

The turn of the century also marked increasing conflicts between countries and transnational drug companies over prices and patents. In 1998-99, South Africa had to confront foreign drug companies and pressures from the US when it passed new legislation aimed at lowering drug prices by allowing for parallel imports of generics and compulsory licensing (Bond 1999; Klug 2008). Brazil also had to face the combined pressures of foreign drug companies and a World Trade Organization panel requested by the United States questioning an article in Brazil's 1996 patent legislation. It was during tough negotiations led by José Serra that Brazil first threatened to use a compulsory license (CL) in order to reduce the cost of Merck's efavirenz and Swiss-based Roche's nelfinavir. The Ministry of Health and the companies reached agreements, as did the Brazilian and US government, but the case exemplifies the increased politicalization

concerning access to AIDS medicines and increasing support from transnational advocacy movements.

Much has been written about negotiations between the Brazilian government and foreign companies. Past work on Brazil's standoff emphasizes the close relationship constructed between Brazilian authorities and social movements (Galvão 2002; Nunn 2007; Wogart and Calcagnotto 2006; Greenhill and Busby 2008). Others have viewed the negotiations in terms of the market strategies of TNCs and potential losses given the size of the Brazilian drug market (Cohen and Lybecker 2005; Wogart and Calcagnotto 2006; Nunn 2007). Another important dimension is the tie-in of local pharmaceutical capabilities to make the threat of compulsory licenses credible (Orsi et al. 2003; Shadlen 2007; Cassier and Marilena Correa 2003). Lastly, we should not discount the interest of Jose Serra in obtaining political capital for his bid to the presidency (Nunn 2007; Wogart and Calcagnotto 2006). In fact, the former Minister of Health has written about the episode (Serra 2004). Some scholars have focused on US pressures on Brazil during the price negotiations and call it the "Merck Case" since the US allegedly requested a WTO panel at the bequest of the US-based drug company (Sell 2003; Richards 2004).

The most coherent account of the first time Brazil threatened a CL and US pressures comes from Nunn (2007) whose work provides a check on validity and a source of empirical data for my account. My contribution will focus on the contribution made by Brazil's domestic drug companies, especially Farmanguinhos; the alliances constructed between Brazilian ministries and social movements; and Brazil's struggles at the World Trade Organization concerning the legality of compulsory licenses. Brazil's "social movement insiders" begin to exploit the "reputational dividends" of its successful AIDS program under the rubric of human rights. By doing so, they extend the arena of state autonomy transnationally and face down corporate and hegemonic power.

New Changes in IPR Legislation

As mentioned in the last section about rolling out ARV treatment, Brazil faced considerable obstacles in terms of government funding. In 1999, for instance, the country experience an economic crisis after it was forced to devalue its currency, and the ensuing fiscal constraints threatened Brazil's AIDS program. Serra, Chequer and AIDS NGOs successfully lobbied Pedro Malan, the Minister of Finance, to release funds to purchase medicines. Besides securing the necessary resources, the other half of the strategy was geared toward reducing costs based on the local production of medicines and reducing the prices paid for imported ARVs. Brazil's public labs gradually substituted imports of the first generation of medicines not protected by patents but faced IP restrictions with respect to second generation ARVs protected by patent. Only with a compulsory license (CL) could Brazilian labs legally market the next generation of products protected by patents.

The first step towards issuing a CL was to improve the legal framework. Presidential Decree 3.201 defined and expanded the uses for issuing a CL by amending Article 71 of Brazil's Industrial Property Law (see Appendix Four). It specified "national emergency" and "public interest" as the criteria for issuing a CL. At the end of 1999, Serra made his first public statement concerning the use of CL:

> There is a Presidential Decree that allows for patents to be broken in the case of abusive prices, and two of our AIDS drugs are candidates for this clause. The laboratories will not be penalized if they lower their prices…The prevention campaigns cost 10 times less than treatment. Not that our motivations are just

> economic…its human, and its about solidarity. But we've got to take costs into consideration. (quoted in Nunn 2007:231)

In 1999, the two drugs were Merck's efavirenz, which cost $2,540 per patient per year, and Swiss-based Roche's nelfinavir at a price $5,585. During the 1999-2001 period when negotiations were taking place, the number of patients using efavirenz rose from 2,460 to 23,313 and for nelfinavir, from 11,761 to 21,717. The total number of patients receiving ARVs increased from 73,000 to 105,000 over the three-year period. Purchases of the two medicines accounted for 22% of the total R$ 568 million spent on acquiring ARVs in 1999—an amount that would increase to 49% of the 2001 ARV budget totaling R$ 501 million.

Besides the issue of compulsory licensing, another important change in legislation made while Serra was the Minister of Health was Law #10.196/2001 that modified articles of the Industrial Property Act # 9.279/1996. This new law aimed to address public health interests by introducing the Bolar Exception and giving ANVISA prior consent to the granting of patents on pharmaceutical products. The Bolar Exception allows a company to carry out all the regulatory tests and approvals necessary to market a product as soon as the patent expires. With this flexibility, a company can obtain a registration to sell a product from ANVISA, although it is still protected by patent. When the patent expires, generic competition can begin immediately, and the price of medicines falls. Also, when the government considers the use of a CL, a local producer could have medicines registered for sale and be in a position to market it to the government.

Law #10.196 of 2001 institutionalized ANVISA's power of prior consent that had been authorized by Presidential Directive (*Medida Provisório*) #2.006 in 1999 and which had been renewed each year. Granting ANVISA the power of prior consent is one of the

more polemical legislative legacies of Serra's era and continues to involve turf battles between two regulatory agencies housed in separate ministries—ANVISA, part of the Ministry of Health, and the National Institute of Intellectual Property (INPI) pertaining to the Ministry of Development Industry, and Commerce. The justification of the prior consent mechanism was to defend the interest of public health and assist the INPI in assessing the novelty requirement for patents on pharmaceuticals (Bermudez and Maria Auxiliardora Oliveira 2004). INPI allegedly did not have the technical capacity to carry out this evaluation. Pressured by local drug makers, Serra lobbied for the Presidential Directive based on the argument that INPI was corrupt and approved every patent application for a pharmaceutical product it received (Wanderly Lima 2008; Raimundo 2008). Although the INPI had been instituted long before the 1996 changes to patent law, the federal agency was under-resourced, had few trained personnel to evaluate drug patents, and thus outsourced most of the applications (Lage 2008). For representatives of foreign drug companies, "prior consent is the biggest aberration that could exist," said Jorge Raimundo (2008), a consultant and lobbyist for the foreign-based pharmaceutical industry group Interfarma.

This review of presidential decrees and new legislation shows how policy makers began to correct a number of problems associated with the Industrial Property Act # 9.279 of 1996. The bill had few of the safeguards outlined in TRIPS and those that were included required modifications. Outlining the grounds for issuing CLs had a direct relevance to the Ministry of Health's negotiations with companies selling patented medicines. The Bolar Exception and ANVISA's prior consent were designed to increase competition with generic medicines, thereby reducing prices for the final consumer and boosting the country's domestic drug industry. These two changes would have important ramifications for the production and acquisition of ARVs. Foreign drug companies were

unhappy with what they viewed as a weakening of IP laws, and the US pharmaceutical industry association PhRMA pressured the US government to take action. Indeed, US Secretary of Commerce William Daley, while travelling to Brazil in 2000 accompanied by Merck's president Raymond Gilmartin, and Pfizer's vice-president for Latin America Ian Read, expressed his displeasure in the CL decree (Aith 2000), but the only issue in which the USTR took action concerned the "local working" clause in Brazil's Industrial Property Act # 9.279 of 1996.

WTO Panel over "Local Working"

Since Brazil's threats of using a CL during negotiations with Merck and Roche coincided with a US panel against the country at the WTO, the conflict over "local working" between the two countries was considered the "Merck case,"[40] and many observers believe that the two are directly tied to each other (Sell 2003; Serra 2004). However, had Brazil not threatened a CL in its negotiations with the two drug companies, the US still would have questioned Brazil's patent legislation in the ambit of the WTO. The panel, nonetheless, crystallized the alliance between Brazilian authorities and social movements interested in access to medicines. In effect, Brazil used its acclaimed universal treatment campaign in its defense at the WTO.

When Brazil passed its Industrial Property Act # 9.279 of 1996, PhRMA praised the legislation but expressed concern over Article 68 that prohibits importation as a form of "local working" for a patented product (Phrma 1998). The provision states the

[40] Although Roche is a Swiss company that marketed the drug, the US still had a direct economic interest in the negotiations since US-based Agouron Pharmaceuticals had licensed the product to Roche. Agouron later became a subsidiary of Pfizer.

government can issue a CL if a patented good is not "worked" in Brazil either through domestic production or permission for its domestic use. The article, in the view of the transnational drug companies, would oblige them to produce all medicines in Brazil and disrupt their strategies of achieving economies of scale through global supply chains. Despite complaints from industry and US officials since the passage of the legislation in 1996, the USTR did not request bilateral consultations until June 8, 2000. The US waited until 2000 before taking the first step in using the WTO system to allow for the completion of the transition process outlined in TRIPS. For Brazil, this expired at the end of 1999. The USTR (2001b) specifically said that the WTO panel would not affect the country's "widely praised anti-AIDS program" and did not affect the use of a CL in cases of public interest or national emergency.[41]

Brazilian interviewees who worked closely on the trade dispute claim that it had been brewing since Brazil passed its new intellectual property legislation in 1996 (Paulo Teixeira 2008; Brandelli 2008). But the US decision to initiate a WTO panel when Brazil's program was attracting worldwide attention provided Brazilian authorities the opportunity to use its AIDS program for its defense at the WTO. Paulo Teixeira (2008), the director of Brazil's National AIDS Program, explained the country's strategy:

> (…) national production started to be the reference for the world. The Brazilian Example! We got together with the Itamaraty [Ministry of Foreign Affairs] and

[41] "On February 1, 2001, a WTO panel was established. Since the establishment of this panel, however, Brazil has asserted that the US case will threaten Brazil's widely-praised anti-AIDS program, and will prevent Brazil from addressing its national health crisis. Nothing could be further from the truth. For example, should Brazil choose to compulsory license anti-retroviral AIDS drugs, it could do so under Article 71 of its patent law, which authorizes compulsory licensing to address a national health emergency, consistent with TRIPS, and which the United States is not challenging. In contrast, Article 68 -- the provision under dispute -- may require the compulsory licensing of any patented product, from bicycles to automobile components to golf clubs. Article 68 is unrelated to health or access to drugs, but instead is discriminating against all imported products in favor of locally produced products. In short, Article 68 is a protectionist measure intended to create jobs for Brazilian nationals" (USTR 2001b: 10).

> came to a conclusion. The National AIDS Program could be Brazil's defense. We did not have the support of all the ministries. The Ministries of Planning and Agriculture did not agree. They thought it inappropriate. (…) We made an agreement with the local NGOs to back up our strategy against the panel and the price negotiations. We also articulated with international NGOs CPTech, MSF, Oxfam and ACT-UP. We were the ones that sought them out. They always did not trust government much, but we were able to get their trust. This began in February and March of 2001.

The NAP coordinated with prominent NGOs when confronting the US. Although there were close alliances between the state body and civil society organizations during the 1990s, the trade dispute over "local working" crystallized the relationship and, for local AIDS NGOS, brought the issue of patents and the price of medicines to the foreground. Activists began to demonstrate in front of US consulates in Brazil, and numerous foreign-based organizations began to lobby the US government to end the WTO panel. Brazil's National AIDS Program also began to extend its activities internationally by reaching out to foreign-based advocacy groups.

Brazil's strategy of mobilizing support from local and foreign civil society succeeded. The US withdrew the WTO panel on June 25, 2001, alleging that Brazil had not actually used a CL based on Article 68 of its patent law (USTR 2001a). In addition, the two sides set up a Consultative Mechanism in which the Brazilian government would give the US advance notice if it were to use a CL based on the "local working" clause.[42] Another factor that weighed in on the resolution of the conflict is that Brazilian diplomats defended themselves by showing that US Patent Code contains "local working" provisions for patents developed with assistance from the federal government and began their formal consultations in the ambit of the WTO for a possible panel against the US

[42] To date, this Consultative Mechanism has never been used but draws attention to how much sovereignty a country has when taking advantage of TRIPS flexibilities.

Brazil's Involvement in the Doha Declaration

The Brazilian government and allied NGO groups not only joined forces against the US pressures at the WTO, but also coordinated efforts in other international government bodies. According to Nunn (2007: 281), there was a "symbiotic relationship" between José Serra and social movements to push their agendas forward: "José Serra and Brazil provided the personal and nation-state leadership that was necessary to propel these reforms forward." International venues included the United Nations Commission on Human Rights, the World Health Assembly and the UN General Assembly Special Session on HIV/AIDS (UNGASS). Transnational advocacy networks needed a leading country to change treatment paradigms at the international level just as much as Brazil needed their support to push its agenda. The coalition between Brazil and international civil society was also instrumental in affecting the Doha round of trade negotiations. Because of the growing awareness of the AIDS crisis, the need to provide inexpensive medicines for treatment, and problems Brazil and South Africa had experienced with foreign drug companies, developing countries were able to place the issue on the trade negotiation agenda.

Serra instructed Brazil's Ministry of Foreign Affairs to find a way for the country to never have to face pressure at the WTO concerning its patent legislation and use of CLs again (Nunn 2007; Serra 2004). The goal was to clarify the use of CLs outlined in TRIPs in terms of public emergency. The term "public emergency" remained vague and subject to broad interpretation. Brazilian negotiators insisted the goal was not to abrogate the TRIPS accord; instead, it was to rebalance the rights and privileges between private

and public interests. Even though it initially resisted the Declaration, the US eventually capitulated but only after threatening to use a CL to purchase ciproflaxin when the anthrax scares struck Washington, DC, in the aftermath of the September 11th attacks. The US Secretary of Health and Human Services' threat to use a CL to lower the prices of the only known medication to fight anthrax and whose patent was in the hands of German-based drug company Bayer exposed the US to accusations of hypocrisy. The Doha Declaration on TRIPS and Public Health was signed a month later, in November 2001, and declared that each member of the WTO had the right to determine the grounds for using a CL and to define what constitutes a national emergency (WTO 2001).

The Doha Declaration did not have an immediate impact on Brazil's negotiations with Merck and Roche, nor did the Declaration fully resolve issues related to parallel importing and exports of medicines. Diplomat Francisco Cannabrava, Brazil's TRIPS negotiator, explains that his country's interest in the agreement was primarily to import raw materials necessary to make generics and not to export medicines (quoted in Nunn 2007: 278). If there is no patent on the product in the country that will export the medicine, a CL is not required, but a decree would be necessary if there is a domestic patent on the product.

There is some debate about the significance of the Doha Declaration. Industry representatives, highlighting that it did not modify any articles of TRIPS, downplayed its significance (Sell 2003), but in legal circles, the opinion is different. Leo Palma (2006), an attorney at the Advisory Centre on WTO Law involved in negotiations leading up to the Doha Declarations, said that the Declaration has the force of law in international trade disputes and provides an extra layer of protection for countries to use CLs.

For Brazil, the Doha Declaration represents the global apex of the "reputational dividends" of its banner AIDS program. It also provided additional legal justification to

use compulsory licenses. In subsequent threats, Brazilian health officials would always invoke the Doha Declaration when declaring a medicine to be in the "public interest." Nonetheless, the accord would not resolve the country's growing dependence on imported raw materials.

Negotiated Settlements with Merck and Roche

The inclusion of patent protection increased the country's dependency by increasing the bargaining power of foreign drug companies and reducing the policy space available to government officials. Up to this point, local industry had developed and produced off-patent medicines. Now, they entered the complicated terrain of developing ARVs that had patents along the entire production chain. Reverse-engineering medicines became increasingly complicated legally, politically, and technologically. While insuring the legal backdrop at the global level for employing a CL, the Ministry of Health sought local production of patent-protected ARVs. Serra said he proceeded with caution when threatening to use a CL to ensure that local production would be able to fulfill the gap. In a previous interview, he said:

> I first had to talk to the Indian drug laboratories to make sure I could get the raw materials from them. Because you can't threaten to break a patent if you can't actually produce the drugs—the problems aren't only legal—there are also technological barriers. (quoted in Nunn 2007: 232)

Serra relied on foreign suppliers of raw material even though he asked if local private industry could develop and produce the medicines. Local pharmochemical labs

such as Labogen and Microbiologica began to develop the synthetic chemical process of both efavirenz and nelfinavir, but later halted their activities (Maçiara 2007; Neto 2008).

From the public labs, only Farmanguinhos and Lafepe presented proposals to produce these medicines in their final dosage forms. In the case of efavirenz, the federal lab confronted problems due in part to legal restrictions and in part to poor raw material. Merck threatened to sue Farmanguinhos after it purchased a generic form of efavirenz's API from India, alleging the acquisition infringed on its patent (Darlington 2001). Merck never took the Farmanguinhos to court, nor did the lab ever complete the development of the drug since a negotiated settlement was achieved soon thereafter. The new price of $0.84 for 200 mg dose represented a 59 percent discount from $2.06. The National AIDS Program announced that the price deal economized $39 million.

Negotiations with Roche dragged on further. Serra refused the company's initial offer and pressed forward with the local development of nelfinavir. Farmanguinhos completed the bio-equivalence tests and produced samples of the finished dosages. "We formulated nelfinavir and had a meeting with Roche and showed them the final product, although we still had to do the scale-up," explained Pinheiro (2008). "But we showed them we were capable of doing it. And Serra threatened the compulsory license." The public lab still required another six months to begin industrial production, and there were no risks of stock-outs since the previous contract with Roche covered the time it would take to do the scale-up. In addition, Farmanguinhos could produce nelfinavir at 40 percent less than the current price charged by Roche.

On August 22, 2001, Serra announced a CL but added that he was still open to negotiations. A week later, Roche (2001) announced that it would reduce the price of the ARV from $1.07 a pill to $0.64—a 40 percent discount comparable to Farmanguinhos'

cost parameters. The Swiss drug company also agreed to move production of nelfinavir to Brazil since the agreed volume of purchases made it economically viable.[43]

The reaction by foreign pharmaceutical companies to Brazil's aggressive approach of copying drugs in public labs and threatening to the use compulsory licenses has varied. On one extreme, executives were upset that their products were being "pirated" and demanded action from the US government to protect their interests (Biehl 2006; Nunn 2007; Raimundo 2008), but executives remained attracted to Brazil's large pharmaceutical market. Although not directly involved in the negotiations at the time, Roche's head of government affairs, João Carlos Ferreira, highlights Serra's interest to launch his presidential campaign:

> We were always under a lot of pressure during the talks. At the time, it was more a public relations issue than having to do with the compulsory license. During the negotiations, Minister Serra had met with the president of Roche, and they seemed to have reached good terms. It did not stop the Ministry of Health from threatening to issue a compulsory license, but the negotiation was already clear. It was more about getting the spotlight for his candidacy.

Brazilian private drug makers came to a similar conclusion. Neto Machado (2008) from Labogen explained: "With respect to compulsory licenses, we began to research and develop efavirenz and nelfinavir because Serra threatened to break the patent, and even used it in his political campaign. He said that he wanted to have a product ready. But since he did not issue the compulsory license, we stopped developing it." Trumpeting a positive government program such as Brazil's AIDS program and threatening to break patents is not uncommon for any politician with future political ambitions. Indeed, Serra

[43] The company later closed the operation due to increasing costs and reduced sales volumes.

left the Ministry of Health in February 2002 to launch his campaign for Brazil's presidency.

Bringing price negotiations to the public spotlight would have lasting effects on corporate strategies.[44] Foreign drug companies that did not have dedicated offices and personnel for negotiating directly with the government would set up a division. However, local autonomy to negotiate contracts would increasingly become more restricted as home offices set pricing criteria. Under the industry-backed Accelerating Access Initiative[45] and other firm-level efforts, global differential pricing schemes were established. Typically, the criteria depended on World Bank classification of a country as high-, medium-, or low-income as well as its HIV prevalence rate. Countries with the highest prevalence rates and lowest levels of income would receive ARVs at the cost of production. Brazil's successful AIDS policies were launching political careers and forcing transnational drug companies to adjust their global strategies.

CHAPTER SUMMARY

Brazil was able to avoid dependency when the AIDS crisis struck. Despite the impact that neoliberal reforms had on domestic drug makers, Brazilian firms, both private and public, demonstrated the technological competence to reverse-engineer and produce advanced medicines. Up to this point, domestic ARV manufacturing capabilities were not

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[44] Marcos Levy, then Director of Public Affairs at Merck Brazil, said, "Merck had been conducting price negotiations with the Health Ministry since 1995, but it was done very quietly back then, and the government still got a good deal. It was José Serra who took this whole thing public when he was running for President" (quoted in Nunn 2007: 279).

[45] In May 2000, several UN agencies entered into a partnership with five pharmaceutical companies (Boehringer Ingelheim; Bristol-Myers Squibb; GlaxoSmithKline; Merck & Co., Inc.; and Hoffmann-La Roche and later joined by Abbott Laboratories) to offer price discounts in 80 countries.

affected by new intellectual property laws. Without this industrial base, Brazil would have been much more beholden to foreign suppliers. Nonetheless, state monopolization of ARV production amidst neoliberal policies resulted in contradictory state policies. The reliance on public labs and the lack of coordinated industrial policies, for example, resulted in the absence of constructive private-public collaboration that could produce innovative AIDS medicines, develop upstream activities for producing active principals, and make Brazil an export platform of ARVs to the rest of the world.

The alliance between activist policy makers and social movements crystallized with domestic groups and extended to transnational advocacy networks when the US applied trade pressure concerning Brazil's patent laws. Had the US not brought a WTO panel against Brazil, it is unlikely that Brazil's domestic AIDS coalition would have gone global. The country's successful treatment program based on local production of ARVs provided a rallying point for activists and policy makers to exploit "reputational dividends." The symbolic power of a middle-income country trumped the material interests of the US and transnational drug corporations. Brazil's power, nonetheless, rested on the credible threat of local production. At this point, private drug makers were not part of the AIDS alliance due to the state monopolization and foreign sourcing of APIs. Nevertheless, the existence of several private domestic companies producing APIs and final dosages increased the country's credible threats (Hasenclever 2008; Lowtroska 2008).

Serra's leadership at the Ministry of Health marked the high point of state autonomy. In the next chapter, I will demonstrate how patent power and market power increased Brazil's external dependency. Meanwhile, the number of patients enrolled in treatment continued to increase, and the use of "reputational dividends" related to Brazil's successful AIDS policies expanded.

CHAPTER FOUR – FRAGMENTED DEVELOPMENT EFFORTS AND EMPTY COMPULSORY LICENSE THREATS (2002-2005)

Brasil é uma esculhambação.[46]

--Luiz Felipe M. Lima, *sanitarista* and ANVISA manager

In this chapter, I seek to explain the increasing foreign dependency of Brazil's pharmaceutical sector due to the impact of intellectual property legislation. During the 1990-2001 period, Brazil was able to legally copy first generation medicines used in the "AIDS cocktail." Over the next few years, domestic drug-making capabilities based on production at public (state-run) labs declined. This process occurred while the number of ARVs offered in its treatment program increased from 13 to 18. Meanwhile, the total number of patients enrolled in the program rose from 125,000 in 2002 to 165,000 in 2005. Due to the increased number of patients and the inclusion of more expensive second-generation, patent-protected treatments, annual ARV expenditures doubled from R$ 496 million to nearly R$1 billion (about $500 million).

The patent power of originator companies and market power of low-cost producers in Asia constricted Brazil's ARV producing abilities, thereby curtailing Brazil's state autonomy. Confrontations between the government and transnational drug companies created another political opportunity concerning the use of compulsory licenses, which resulted in increased societal mobilization. Despite the fever pitch of activists (both inside and outside the state) who maximized the use of Brazil's "reputational dividends"—the symbolic resonance of Brazil's successful AIDS program—the government once again backed off the use of compulsory licenses. The

46 "Brazil is an *esculhambação*." The Michaelis Moderno Dicionário Português-Inglês (Portuguese-English) defines *esculhambação* in the following way: *[eskuλãbas'ãw] sf (pl esculhambações) Brazilian, slang 1. disorder, confusion, disarray, anarchy. 2. reprimand. 3. demoralization.*

confrontation renewed the alliance between social movement insiders and human rights activists, and revealed the need to include another domestic ally: local pharmaceutical industrialists.

THE NEW PRESIDENCY OF LUIS INÁCIO 'LULA' DA SILVA

Jose Serra, despite attracting international attention in leading Brazil's struggle against AIDS and defending countries' rights to use TRIPS flexibilities, suffered a loss in Brazil's 2002 runoff presidential elections. Left-of-center candidate Luiz Inacio 'Lula' da Silva received 61% of the votes against Serra. After eight years of neoliberal economic policies by Fernando Henrique Cardoso from the PSDB, Brazilians opted for the candidate from the Workers' Party (*Partido dos Trabalhadores*-PT) who promised to redistribute Brazil's wealth and expand social programs tackling chronic poverty. Lula, whose candidacy was backed by social movements interested in addressing Brazil's social inequities and the local bourgeoisie affected by neoliberal policies of the past administration, was Brazil's president to have come from the country's popular classes. The new administration, however, did not rescind past neoliberal reforms. Rather, Lula streamlined and expanded existing social programs and kicked off industrial programs to support strategic sectors of the economy.

Policies for treating AIDS patients were not expected to change significantly in the presidential transition, since the program had already become institutionalized and many of the directors of the National AIDS Program had strong ties with the social movements that supported Lula and the PT. In fact, many activists believed that Lula's administration would be more aggressive in its pursuit of compulsory license for AIDS

medicines. The one concern was that, since Serra had used the AIDS banner during his political campaign, the new administration would undertake personal changes at the Ministry of Health affecting the local production of ARVs.

Restructuring Pharmaceutical Policies and Reorganizing Public Labs

Humberto Costa, a physician from the northeastern state of Pernambuco, was chosen to assume command of the Ministry of Health in Lula's new government. He was not considered as strong or as capable a politician as Jose Serra, but a new group of *sanitaristas* had entered the top positions of the Ministry. Noberto Rech (2008), leader of the pharmacists' trade union from Santa Catarina state and affiliated with PT's political ally, the Communist Party of Brazil (*Partido Comunista do Brasil*—PCdoB), explained in an interview the changes made in pharmaceutical policies. First, the transition team comprised of Rech and others decided to create a new Secretary of Science, Technology and Strategic Inputs within the Ministry of Health under which the Department of Pharmaceutical Assistance would be subordinated and given responsibility for implementing pharmaceutical policies.

Second, the Ministry consolidated the 23 different programs related to pharmaceutical assistance left over from the Serra era. Internal debates concerning which medicines should receive priority reflected an interest in local production to insure sustainability of strategic health programs:

> In the case of the medicines considered strategic or being used in strategic programs, we wanted to review the mechanisms of acquisition, identify the priorities of these medicines, their costs, and what actions we could do for

> inducing public production or private production of these medicines in the country, and thus give sustainability of these medicines, and that is where AIDS comes in. (Rech 2008).

Regarding the network of 18 public labs, the Ministry of Health continued to invest in their modernization but with some modifications. The Umbrella Project (*Projeto Guarda Chuva*), the investment program undertaken during Serra's administration, only invested in new machinery and increasing productive capacity, Rech (2008) explained. A new round of investments went into new technologies, improving human capital, and bringing the public labs up to date with increasingly stringent regulations published by the National Sanitary Surveillance Agency (*Agencia Nacional de Vigilância Sanitária*—ANVISA). In fact, investments in public labs increased significantly in subsequent years. Table 3 shows that during Serra's administration, annual investments did not top R$ 15 million. But the Workers' Party kicked off the Modernization Program of Public Drug Production in 2003 and investments jumped from R$ 36 million during their first year in office to around R$ 78 million in 2004. Total production of medicines increased but production of ARVs fell—a topic I address in a subsequent section.

Table 4: Investments (R$) and Production (pharmaceutical units) in Public Labs

Year	Investments (R$ million)	Production (billions of units*)	Production of ARVs (millions of units*)
1997	-	2.1	71.9
1998	-	2.3	86.2
1999	-	2.5	103.9
2000	-	3.5	136.8
2001	14.5	4.0	202.4
2002	11.4	5.3	194.2
2003	36.0	5.3	153.6
2004	77.9	5.6	118.5
2005	60.7	7.5	209.0
2006	67.9	7.8	163.2
2007	56.4	4.8	163.3

* The Ministry of Health defines a pharmaceutical unit based on its pharmaceutical form; that is, for solids—one pill, one capsule, one vial containing sterile powder; for liquids—one vial; for semi-solids—one collapsible tube; for intravenous—one blister, one vial. The unit is not comparable to private sector units. Source: Ministry of Health (2008).

Despite the investments in capacity and technology, Brazilian labs were unable to compete with international price trends. While Brazil's entrance into the generic ARV market in the late 1990s reduced the per patient per year prices to less than one-third of the $15,000 of US retail prices, Indian suppliers were offering prices in the hundreds of dollars for the same medication. One calculation estimates that Brazil paid an excess amount of $110 million from 2001 to 2005 for locally produced generics compared to international reference prices paid by other low- and middle-income countries (Nunn et al. 2007). Another study showed a difference of $57.6 million just in 2005 (Felipe Marques and Hasenclever 2006). While aggressive negotiations with patent holders resulted in savings of $1.2 billion (Nunn et al. 2007), it still begs the question why officials continued to pay more to public labs instead of economizing resources by sourcing ARVs from abroad.

Brazil's continued support for its public labs are associated with maintaining state autonomy and avoiding foreign dependency. Specifically, having local production of medicines allows for a tougher negotiating stance. The $1.2 billion in savings would not have been achieved without Brazil's ability to produce ARVs in public (or private) labs. Rech (2008) explains the Ministry's decision to continue the policy of acquiring ARVs from public labs:

> In the moment that I just substitute national production, despite being a little more expensive, for purchases abroad that are in principle less expensive, through time I will discourage the [domestic] industrial park—not just in the public but also in the private sector—and the result will be its subsequent contraction. What does this mean? Loss of technological capacity implies losing the capacity through time to have a more active role in negotiations. Therefore, those medicines which at first were much less expensive purchased abroad, through time—insomuch as the national industrial park be it public or private is shut down due to a decision to import—certainly, and this is a rule of the capitalist world, a product's price will tend to increase. This would place us in a situation of being hostages to decisions made abroad.

Although international reference prices for AZT and other commonly used medicines to treat AIDS began to fall in price, Brazilian health authorities believed it was necessary to continue investing and purchasing medicines made by public labs in order to boost their bargaining position.[47]

One reason Brazilian public labs are not competitive is their inability to achieve economies of scale.[48] The country's network of 18 public labs is controlled by distinct

[47] Brazil, nonetheless, tapped into cheap international markets when it joined forces with other South American countries and engaged in collective negotiations in order to obtain better prices. For an evaluation of the first round of collective negotiations in 2003 and the difficulties encountered, see the study carried out by the Center for Pharmaceutical Policies (Cristante, Osorio-de-Castro, and Oliviera 2008: 8).

[48] Other reasons include the lack of incentives for administrators in public labs to reduce costs, poor production planning, lack of administrative flexibility illustrated by Law 8.666, and the Ministry of

branches of government at the federal and state levels. Under Serra, the allocation of ARVs was centralized under Farmanguinhos (FM) and the Brazilian Official Pharmaceutical Lab Association (*Associação Brasileira de Laboratórios Oficiais do Brasil*—ALFOB. The new administration attempted to streamline output from the public labs (not just ARVs but other medicines used in public health programs). Additionally, the new administration felt that the federal lab had concentrated too much ARV production and began to re-distribute supply contracts to other public labs (and to a lesser extent other national private labs) (Felipe 2008).

Efforts to better coordinate the network's production failed, but ARV purchases from other public labs increased at the expense of FM. In 2001, the federal lab produced 135 million pharmaceutical units of ARVs worth R$ 145 million, more than double the amount procured from other public labs combined. By 2005, the situation had reversed: other public labs were contributing triple the amount relative to FM. The changes had significant, unforeseen consequences that would increase the country's external dependency. Instead of working together, public labs began to compete against one another for federal contracts to supply ARVs, which were considered a high-end product compared to other drugs. Pedro Rolim (2008), former director of production at Lafepe, described the situation: "There was never development as a group of public labs acting together. It ended up being a little cannibalistic: Each one seeking out their own development and pride since they have distinct juridical bases."

Problems Sourcing Raw Materials

Health's willingness to pay more for ARVs to cover the fixed costs of public labs (Clinton Foundation 2006).

One area that revealed Brazil's dependency as a result of increasing globalization is problems sourcing raw materials—the active principal ingredients (APIs) and chemical intermediates required to make final dosage forms. As described in Chapter Two detailing Brazil's pharmaceutical industry, South America's largest country has a weak pharmochemical base. Brazil is home to approximately 550 drug firms that combine APIs with inert ingredients to make the final product but has only 23 firms that produce APIs and only a few of those are completely verticalized, that is capable of producing synthetic chemicals, APIs, and final dosage forms. The one notable exception of verticalized production is the private domestic firm Cristalia, which also produces ARVs. It is estimated that imports account for 80% of the domestic pharmochemical market (Chamas 2005). There has been growing dependence on imports from China and India, but since they consist mainly of low value-added products, they do not account for more than 25% of total imports (ABIQUIF 2009).

Most public labs produce low value-added medicines so they tend to rely more on Asian raw material suppliers. The director of the public lab Funed said that two-thirds of their inputs come from China and India (Pereira Gomes 2008). A few, such as Farmanguinhos (FM), have in-house laboratory scale operations to produce small batches of APIs for some orphan drugs, but industrial-scale production of bulk active principals goes beyond FM's current capabilities.

Sourcing of foreign APIs not only increased dependence as market power of Asian suppliers grew but in some instances put the country's universal AIDS treatment program at risk. The factors that led to this situation were, first, that several part of the administrative changes enacted by the new PT government that came into power in 2003 affected how public labs obtained active principals. During the scale-up of ARV production under Minister Serra, procurement of raw material was, to a large extent,

centralized in Farmanguinhos. When the system moved towards decentralized purchases, economies of scale were lost. But possible benefits of spreading risk (i.e. faulty material or delivery delays) were not achieved since most labs ended up buying from the same suppliers (Lowtroska 2008).

Second, global demand for ARVs sky-rocketed as national and global efforts attempted to replicate Brazil's success in other parts of the developing world. Multilateral initiatives included the Global Fund to Fight AIDS, Tuberculosis and Malaria (2002), the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) "3 by 5" strategy was jointly launched in December 2003 with the aim of having 3 million people on treatment by 2005, and US President's Emergency Plan for AIDS Relief (PEPFAR) launched in 2003. Marco Vitoria Antonio (2006), who once helped establish Brazil's National AIDS program and now works as a medical officer at the WHO, warned that there could be a "stock out, not because of a lack of political will, but because there are not enough producers of APIs." Rising demand for APIs strained Brazilian procurement already encumbered by highly restrictive rules governing public tenders.

The third reason is the strict tender laws that favor awarding procurement contracts to suppliers that offer the lowest price. Nearly all the different groups interviewed for this project complained about Public Procurement Law 8.666 of 1993. The problems of the rigid tender law on public labs' contracts have attracted the attention of Brazilian academics (cf. Felipe Marques and Hasenclever 2006). My review coincides and supplements their account. After massive corruption scandals in the early 1990s, Brazil passed new rules governing all contracts carried out by the public sector.

The Public Procurement Law establishes formal procedures to avoid corruption. The same legislation applies to the whole public sector whether a municipal government

or state enterprise; consequently, departments or agencies cannot adopt internal rules. Also, tenders cannot distinguish between foreign versus local suppliers nor impose technical restrictions, such as quality, apart from price criteria. In sum, price auctions award contracts regardless of other criteria. When carrying out auctions for the procurement of raw materials, public labs are legally obliged to award contracts based solely on price and then analyze quality afterwards.[49]

Interviews carried out with local pharmochemical industry and managers of public labs revealed the problems associated with the rigid process of awarding contracts. Neto Machado (2008) from São Paulo-based Labogen explained that merchants connected to trade networks in Asia would always win the auctions. "The Chinese representative would hear all the bids then get on his phone and place a lower bid than all those that were submitted." In addition, Brazilian firms were placed at a disadvantage due to strong competition from Asian competitors and a complicated tax code that favored imports:

> When Lula came to power, carrying out international tenders became the standard. I did a spreadsheet and I showed Furlan [Minister of Development, Industry and Trade] that I could take advantage of drawback measures, sell my product to the Cayman Islands, re-sell back to Brazil and be competitive with the Indian and Chinese competition. But I would not do so because I would get in trouble with Brazil's tax authorities. There were even some instances that I would export my product to China and then the Chinese would sell it back to Brazil. They said they could still make money because they receive a lot of fiscal benefits from their government. I asked Furlan to begin anti-dumping measures against China in the case of DDI [didanosine], but he said that he could not do anything

[49] "As a consequence [of Law 8.666], national suppliers have been losing space to Chinese and Indian producers that offer lower prices since they fulfill fewer phytosanitary demands. This dependence has become more uncomfortable during phases of rising world demand that has been occurring, in which the government feels obliged to ration the consumption due to scarcity of raw material" (Felipe Marques and Hasenclever 2006: 13-14).

> to favor a small industry such as mine in the face of the Chinese that import billions of dollars of Brazilian steel, soy, and other exports…(Neto 2008)

Labogen's experience provides insight into how the current global economy favors exports based on tax credits at the expense of local producers. Drawback measures allow companies to assemble products in export processing zones without having to pay taxes on the value added. In extreme forms, fiscal benefits transform into export subsidies that result in dumping.

The account also highlights China's growing market power in the global economy. The ARV commodity chain links workers from the Chinese hinterlands to Brazilian patients. Lelio Maiçara (2007) explains the dynamic process: "The Indians obtained scale and acted in world markets as large suppliers and now obtain their raw materials from the Chinese. The Chinese that speak English buy the materials from the non-English speaking Chinese in the interior. It is a chain that starts in China and goes to the Indians." Between January 2002 and February 2005, foreign suppliers won 82% of the 68 auctions to supply APIs for making stavudine, didanosine, indinavir, lamivudine, and zidovudine amounting to $26 million in contracts. Just for the months of January 2004 to February 2005, foreigners won 93% of the contracts worth $21.2 million (Lages 2007). Maiçara, a representative of Brazil's pharmochemical industry, alleges that Brazilian API suppliers would be as competitive as foreigners if they were to circumvent the commercial intermediaries and obtain basic raw materials from the interior of China.

The sourcing of APIs by public labs became increasingly problematic, ranging from issues with pre-qualifying suppliers to allegations of corruption. Public labs operated by state governments tend to confront most of the problems of pre-qualification. Pedro Rolim (2008) from Lafepe recounts his experience with poor raw material:

> We always received a lot of raw material that was of bad quality, contained impurities, etc. If you don't have a good analytic methodology, then you let these impurities get by. Doing pharmaceuticals is not like following a recipe to make a cake. You always have to evaluate every step. We never sent our raw material to be re-processed. We sent it back to the supplier and told them to send us another batch. It is a prostitute market. They show one product that is good quality, and then when they send the whole batch, it is of horrible quality. It is not possible to identify a "picareta"[cheat] during the tender process. If we reject some raw material, it could take up to 15 days, at best, to get another batch.

In one instance, a South Korean supplier that had their product rejected bythe public lab Vital Brazil located in Niteroi, Rio de Janeiro, sent the same item to Lafepe in Pernambuco without even removing the rejection label off the top of the box! Purchasing raw material at the lowest price did not economize resources. Maçiara (2006) estimates that public labs pay an extra 30% on the cost of producing ARVs due to the need of re-processing or purifying poor-quality APIs.[50]

Brazil's endemic corruption has also found its way into the API market. Although interviewees at public labs and government as well as the private sector denied any direct knowledge of corrupt practices, they did not rule out the possibility. Hasenclever (2008), an economist at UFRJ, explained the process:

> The money made by the public labs ends up in a public fund. The difference is between the price paid for raw material and the price sold to the Ministry of Health. The money can then be used to finance political campaigns. This is "Samba do Crioulo Doido"[or "Samba of the Crazy Creole"]. Much of the accounts do not pass through the TCU [Public Audit Court]. Public labs ended up buying raw material from the Indians and Chinese and instead of purchasing at

[50] This provided a new niche for some Brazilian pharmochemical firms, such as Labogen, which became a service provider re-processing imports of APIs.

> the price offered, would mark up the price, i.e. overbill, so that they could remain with the difference.

Evidence for her claims came from a federal prosecutor Jose Vagos. The *Roupa Suja* [Dirty Laundry] investigation, which concluded in 2005, uncovered a price-setting scheme between allegedly rival suppliers and kick-backs to employees of public labs. Claiming that all public labs are corrupt at all times is beyond the scope of this dissertation. If public-private partnerships remain suspect due to fraudulent practices, the ability to construct a "triple alliance" remains problematic.

In sum, Brazilian public labs became increasingly dependent on Asian suppliers of the key ingredient, the API, for the production of its AIDS medicines. Procurement decentralization caused by each facility purchasing its supplies individually only serviced to fragment a streamlined process organized by Farmanguinhos. This shift in procurement occurred at a time when global demand for ARVs became overheated. Previous stable supplies of raw material from India and China were disrupted as these foreign producers rushed to fill a jump in demand and started to out-source production to poor-quality suppliers. A strict interpretation of Public Procurement Law 8.666 forced Brazilian purchasers to remain beholden to lowest-priced foreign bidders even though quality dropped.[51] The Brazilian pharmochemical industry lost an opportunity to grow and instead became a service provider purifying imported raw material. The Achilles' heel of Brazilian local production would threaten its universal access program but also provide an opportunity for Brazil's AIDS coalition to add another partner.

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[51] An opposing view concerning the poor quality of Asian suppliers comes from the ex-directors of Farmanguinhos Eloan Pinheiro and Nubia Boechat who praise the quality of Indian firms like Hetero and claim that the problem with poor quality stems from way public labs write up their call-for-tenders. If these labs had included more rigid product specifications, they would not have had so many problems. In either case, it is likely that the experience of the federal lab in this area was lost when raw material purchases were decentralized.

Supply Problems of the National AIDS Program

At the start of 2005, Brazil's model treatment program was placed in risk. Part of the problem resulted from the rationing of medicines due to the aforementioned problems related to foreign supplies of APIs. Another issue was that the federal government was late in approving the 2005 budget the previous year. Since public labs rely on the government for working capital to purchase inputs, production timeframes were pushed back. According to Carlos Alberto Pereira Gomes, the president of public lab industry association ALFOB, the delay in closing the contracts with the Ministry of Health only occurred in December and not in October when they typically occurred. "We buy by the Law 8.666, so it was delayed. Since the process of signing contracts got backed up, the purchase of raw material took place later," he was quoted as saying in Folha Online news service (Leite 2005). The delay in receiving funds to produce medicines affected 30,000 patients, the news service reported.

Responses to the stock-outs reveal the importance of maintaining the "reputational dividends" of Brazil's banner AIDS program. Failing to manage the symbolic currency of the program could weaken ministers of government as well as provide opportunities for image management by drug corporations. Supply problems revealed management problems and political infighting at the highest levels of government.

An editorial in the *Estado de São Paulo* newspaper (2005), often critical of the left-leaning PT government, underscored the "screaming technical incompetence of the Minister Humberto Costa" and the "administrative disorder that delayed in almost three

months purchasing orders and the release of funds for the public labs". Costa initially blamed Indian suppliers of raw material for the disruption, while former and current Ministry of Health officials all began to point blame at each other. Asked about the reports of delays in the delivery of raw material, Costa responded: "If we had been advised on the first day about the delays, we would have taken the measures we took now" (Constatino 2005). The Ministry ended up importing three tons of medicines from Argentina using contacts established by Pedro Chequer when he helped set the neighboring country's AIDS efforts before returning as director of Brazil's National AIDS Program.[52]

The Ministry's budget and administrative problems were not restricted solely to public labs, but also affected the purchasing of medicines from foreign companies. In early 2005, health officials claimed that stock outs of patented ARVs were the consequence of companies not lowering their prices. The situation placed companies in a dilemma but also presented a public relations opportunity. The difference in tactical responses can be seen at the company level. Gilead, the supplier of tenofovir to the program, ended up trading accusations with the Ministry of Health. Health officials said the company did have its importation papers in order and could be fined, whereas company representatives claimed the ministry did not have $6 million available for payment (FSP 2005).

Bristol Meyers Squibb (BMS) saw the ministry's budget problems as an opportunity to improve its relationship with the public and to present itself as a partner to Brazil's AIDS program. Antonio Salles (2008), director of corporate relations for the company's local division explained the problem and his company's approach:

[52] Brazil later paid back the Argentine government with R$ 3.9 million worth of ARVs.

> Because the budget wasn't approved, the government didn't purchase anymore drugs. I kept warning them: look you have x number of days left of product. I warned Antonio Alves, at the time who was executive-secretary of the ministry. Of course when this hit the news, the government didn't want to look bad. When the Estado de São Paulo newspaper contacted us, we of course had all the letters we sent warning the government. So the government asked us to deliver the product and sign the contract at the time of delivery. So we sent a plane from Indiana with atazanavir. So there was a picture in the Estado de São Paulo, with the product being offloaded… If you look in the newspaper, Bristol made a statement saying there was no contract with the government. We even advised all the ONG's what was going on. We have a very good relationship with the NGO's. Mario Scheffer [from Grupo pela Vidda] can confirm this.

Despite the positive relationships cultivated, companies like BMS still could not win the ideological battle concerning patents. Asked about the rationing of medicines, Rubens Duda, President of São Paulo State AIDS/NGO Forum, was quoted as saying: "The movement does not want to know the motive behind the stock outs; it wants a medicines policy. We want the breaking of patents," (Leite 2005).

HEALTH MINISTERS BACK OFF COMPULSORY LICENSES

Brazil's problems with local production of ARVs compounded the country's ability to take advantage of flexibilities outlined in the TRIPS agreement. In this sense, state autonomy was constrained due to the lack of domestic alternatives. In 2003 and 2005, Brazil threatened to issue compulsory licenses (CLs) for the purchase of patented AIDS medicines, but on both occasions, the Minister of Health backed off the threats and reached a negotiated settlement. The two events reveal the problems associated with local production and increased dependency on foreign suppliers.

Besides the budget and administrative problems at the Ministry of Health, there are several other factors that contributed to the failure to take advantage of the TRIPS flexibilities. These include higher standards in pharmaceutical production, perceived US retaliation, and, most importantly, the inability to obtain access to patented inputs used for making drugs. Nonetheless, the on-going problems with local production and the continued government clashes with foreign companies over high-priced, patented medicines increased civil society's mobilization around issues of patents and local production.

Changing Negotiating Strategy Based on Imports

When the left-of-center government of Luiz Inacio Lula da Silva assumed power on January 1, 2003, social movements felt invigorated by the prospect of more progressive social policies. Although the National AIDS Program had already established close ties to civil society groups, activists expected the new administration to follow through with threats against transnational drug companies.

The AIDS coalition would be disappointed. Instead of ending patent monopolies, Brazil's clashes with Abbott, Gilead, and Merck revealed additional obstacles in the development and sourcing of generic alternatives, especially given the short time horizons of drug negotiations. Alexander Grangeiro (2008) who was in charge of the National AIDS Program in 2002-2003 explains that his agency became the "protagonist" in terms of negotiating with foreign drug companies and evaluating different policy options at the start of Lula's first term in office:

> We presented two options to the companies: One, reduce prices, or two, provide a voluntary license for production of the medicines in Brazil. Within this informal group we determined that production of any of these drugs would take at least a year. Lopinavir was the most complex to produce while the other two easier. Nelfinavir and efavirenz were already available in generic form in India and China, but they did not have a market to sell the medicines because Third World countries were just starting to use these ARV drugs and there was low demand for them. The Indians had them available on the shelves but they had not passed all the tests of bio-equivalence and bio-availability. People from Farmanguinhos and ANVISA (the regulatory authority) went to India to evaluate these medicines.
>
> This is a vicious cycle: without a market they did not have production ready, and in an emergency they wouldn't be ready. To produce these medicines in Brazil, it would take one to two years. Farmanguinhos was in a transition phase, and other projects were paralyzed at Farmanguinhos. So the other option was to import the medicines. (…) At the time the Brazilian law did not allow the importation of the drugs so we started to work on changing the laws related to compulsory licenses.

This quote by Grangeiro highlights a number of theoretical points related to TRIPS, local production, and ensuring access to medicines. First, Brazil issued Decree #4.830 in 2003 that allows for parallel importation of products when a CL is issued. When Brazil had threatened CLs in previous years, the threat was backed by capability to produce the medicine locally. Importation was not considered a possibility because it was illegal under the patent legislation in force at the time. A drug company could legally restrict importation but not local production! The new decree allowed Brazil to import drugs from countries in which the product was not protected by patent. Since India and China took advantage of the complete transition process to become TRIPS-compliant (i.e. waited until 2005 before recognizing patents on pharmaceutical products), they reverse engineered and developed several second generation ARVs that were protected by patent in Brazil but not their countries.[53]

[53] Appendix 4 includes a list of TRIPS flexibilities and related Brazilian legislation.

Second, officials from the Ministry of Health took the lead in modifying intellectual property law. It is important to highlight that domestic, privately-owned drug companies did not sponsor the legislation, nor did they block it, as other scholars have argued (Shadlen 2009).[54] Representatives from the transnational drug industry, however, were vehement in their opposition to laws that increase the use of compulsory licenses. Jorge Raimundo (2008) from Interfarma, an industry organization representing the interests of foreign drug companies, called the decree an "aberration." Despite changes in government, Brazilian health officials especially from the AIDS program continued to press for increasing humanitarian safeguards in domestic IP laws. There has a continuous learning curve concerning the use of TRIPS flexibilities that resulted from price negotiations officials held with patent holders (Maria Auxiliadora Oliveira, Chaves, and Epsztejn 2004).[55]

Third, Brazilian officials began to rely more on imported versions of patented drugs than on local development and production to guarantee the sustainability of its treatment program. During the 1990 to 2001 period, Brazil demonstrated its capability to quickly copy medicines and ramp up production. The reasons for its success include competent scientists and engineers in both private and public sector companies attracted to the nation's call to fight the epidemic, capable politicians backed by a mobilized civil society who fought for sufficient resources for R&D and production, and most importantly, the first ARVs used in triple therapy consisted of medicines not protected by

[54] Shadlen (2009), however, notes that a lawyer from Brazil's fine chemical industry association ABIFINA drafted Decree #4.830 outlining the uses of a compulsory license.

[55] Incorporating TRIPS flexibilities were not always successful. In 2002, Brazil passed Law 10.603 which grants protection for undisclosed data drug firms provide to regulatory officials in order to obtain marketing approval. Extending the timeframe for protecting undisclosed data—considered a TRIPS-plus measure—restricts competition from generic drugs markers, which could lead to lower prices. The law was passed after Jose Serra had left the Ministry of Health to campaign for the presidency and before new PT officials had assumed control of government. The law may have been more difficult to pass had it not been pushed through during this window of opportunity between administrations.

patent. In the first confrontation over the price of patented medicines and threats to issue a CL, Brazil was able to make a credible threat of local production of Roche's nelfinavir. The initial face-off, despite ending in a negotiated settlement and price reduction, foreshadowed the challenges in subsequent years.

Decree #4.830 of 2003, which revealed that Brazilian authorities were going to rely on Indian suppliers of ARVs, had contradictory affects. On the one hand, it showed that local production capabilities had weakened. A new director, Nubia Boechat, took control over Farmanguinhos and began to reorganize operations. Even without the temporary disruptions in the federal lab's operations, developing and registering a new formula became more time consuming. "In 2001 the drugs could have been produced without having to pass certain quality tests," explained Grangeiro (2008). Both pharmaceutical companies and some NGOs, he added, attempted to discredit or challenge the quality of generic drugs. "So in 2001 it was much more politically feasible to produce these drugs. In 2003 it was unthinkable," he said. ANVISA, created in 1999 to regulate the pharmaceutical market, had established more stringent guidelines for registering products by 2003. During the reign of Eloan Pinheiro at Farmanguinhos (1994-2002), most quality tests were carried out in-house without ANVISA's external verification.

On the other hand, Decree #4.830 improved the Brazilian governments bargaining position. The perception was that drug companies felt they had an advantage during price negotiations since Farmanguinhos was in a transition period, and it was unlikely that President Lula would spend political capital on a CL during his first year in office and potentially scare off foreign investors. The leftist president's arrival to power had already alarmed investors who threatened an economic meltdown by speculating against the country's currency. Grangeiro (2008) reveals the dynamic in the political process

between the Minister Health Humberto Costa, Jarbas Barbosa (Secretary of Health Surveillance at the Ministry) and President Lula:

> Lula said 'Brazil is not going to be held hostage'. 'If we need to, we will do a compulsory license.' But there was a lack of continuity between Lula's discourse and what Costa was saying. (…) Jarbas Barbosa also was against the compulsory license. Other Ministers were on the fence, but Jarbas said it was like an atomic bomb: 'The compulsory license is not to use, it would lose its' effect. Kind of like the compulsory license is more effective as a deterrent.

Although many health officials knew they could rely on support from international civil society if they were to move against patent monopolies, many policy makers had not reached the *cognitive liberation*, i.e. the subjective realization of the political possibilities at the current political conjuncture.[56] Nonetheless, the 2003 decree allowing for parallel importation was effective in forcing drug companies to lower prices. Negotiated settlements with patent holders finalized in January 2004 allowed the Ministry of Health to save R$ 299 million, representing 37% of its ARV budget (Maria Auxiliadora Oliveira et al. 2004). The savings represent the enrollment of 20,000 new patients in the AIDS program and two additional ARVs, tenofovir and atazanavir, to be included in treatment regimens.

Research and Development of New and Patented ARVs

After having successfully developed and produced most off-patent ARVs, the question became which patented medicines to develop and how to successfully continue

[56] The concept of *cognitive liberation* comes from social movement literature (see McAdam 1982) but has the same relevance in this context given policy makers' fears of retaliation and unforeseen consequences.

the program. But in subsequent years, Brazil's public labs achieved limited success with second generation ARVs. Brazil passed Law 10.196 in 2001 that allows a drug company to carry out all the necessary tests and procedures required for the registration of generic versions before the patent expiration. Despite the incorporation of this TRIPS flexibility known as the Bolar Exception, why did Brazilian firms not make greater use of this allowance?

Besides the ratcheting up of quality standards set forth by ANVISA for obtaining product registration,[57] another factor was administrative changes at Farmanguinhos. Eloan Pinheiro, whohsf directed the facility since 1994, was forced to leave at the end of 2002. The new PT administration felt that she was too closely tied to Lula's former presidential challenger. Indeed, Jose Serra requested Pinheiro to continue as FM's director until the presidential elections, contravening the institute's rules to vote on a new director every three years. An adjunct director assumed control for three months until Farmanguinhos' employees elected Nubia Boechat, an organic chemist and FM career employee, as the new head of the federal lab. She removed personnel associated with Pinheiro and brought in new researchers and scientists. It is not uncommon for a new administration to enact personnel changes, but interviewees acknowledge that the changes made were significant. Boechat (2008) adds that the company was in disarray even before she assumed control since the interim director, in power for three month period, did not sign any contracts to obtain raw material nor make any operational decisions for the year.

The transition of a new administration under Boechat could not have come at a more inopportune time. The Ministry of Health was redirecting purchases away from FM

[57] ANVISA was not only tightening product standards to improve consumer protection on the domestic market. The regulatory agency was looking to increase the quality of Brazilian pharmaceutical products on global markets (cf. Flynn and Andrade de Oliveira 2009).

to other public labs. As a result, the substantial sums of money brought in from ARV purchases during Pinheiro's administration and which she used to finance other R&D projects was drying up. "In 2003, the resources available for R&D disappeared," Boechat (2008) claimed. When Pinheiro left Farmanguinhos in 2002, she had eight projects related to ARVs in development. Boechat said she continued to invest in ARV development, but there were no new ARV launchings under her watch.[58]

Other public labs operated by state-run governments did not undergo complicated transitions like Farmanguinhos and were in a position to continue their research and development, but there was no coordination from the federal authorities directing state labs to invest in specific ARVs. Indeed, with the Ministry allocating more production towards other public labs, they would have more resources for R&D. The managers of public labs, however, did not want to risk investing scarce resources without purchase guarantees from the Ministry of Health.

The situation of São Paulo state lab Furp, a close partner of FM, is emblematic of the situation. Ricardo Oliva (2007), Furp's director, explained the importance of federal contracts and inherent investment risks without a coherent policy for strategic medicines. In 2005, Furp sold R$ 50 million in medicines including ARVs to the Ministry of Health and R$ 22 million the subsequent year. The revenue difference had a significant impact on the laboratory's cash flow. He stated:

> Public companies do not have venture capital…Am I going to invest in efavirenz? I would not even think about it...I am not going to do it because I don't have a market…In principle, nothing stops me from producing in advance, waiting for

[58] During this time, Farmanguinhos only registered one product. Boechat adds that ANVISA's stricter regulations were also a factor. "Eloan was able to approve eight medicines in one year. Afterwards, ANVISA began its operations and it became difficult even to renew registrations. I think the only item I was able to launch was a syrup form of ferrous sulfate," she said.

> the moment for the patent to fall or to support the development of the national pharmochemical industry or to be used as a political instrument for negotiating price. Can it be done? Of course, just as long as you have a view towards that objective.

> Now I cannot produce in advance and [the Ministry of Health] turns to me and says: "We are not going to buy from you. We are going to buy from Farmanguinhos." I can't do this. I am going to invest some US$ 2.5 million in two years to do any ARV in advance, to do the reverse engineering and necessary investments...have this waiting on the shelves, and afterwards [the Ministry of Health] turns to me and says: "I am going to do this with Lafepe and Farmanguinhos." I lost US$6 million from the government of the state of São Paulo that could have been used to develop something else!

Although São Paulo state has the largest AIDS populations, Oliva says that it would be a waste of the state government's resources if it were to develop and produce ARVs just for distribution within the state because the program has been federalized. "The Ministry of Health buys the medicines and distributes them," he said.[59]

Coordinating R&D and staying abreast of changing treatment protocols are internal problems related to administering a complex social program. These administrative challenges are exacerbated by external constraints imposed by originator companies who were able to use their patent power to restrict the development of generic copies. Despite the Bolar Exception allowing for registration of generics before a patent expires, foreign drug companies filed several injunctions restricting access to patented

[59] Another state lab, Lafepe based in Pernambuco, risked developing new ARV formulations, but the results could not keep pace with changing treatment protocols. In 2004, the company registered a 200mg formulation for efavirenz, but in the same year the NAP therapeutic consensus began recommending a 600mg formulation recently launched by Merck. Instead of taking three tablets a day, the new formula required patients to only take one tablet, thereby improving treatment adherence. Changing protocols affect not only patented products, but also the development of fixed-dose combinations. Pedro Rolim (2008) said he had to drop development of the three-in-one pill comprised of stavudine-lamivudine-nevirapine after NAP stopped recommending the usage of stavudine. The R&D projects were not a complete waste since they did contribute to graduate student training and advanced Lafepe's learning process, which then could be applied toward developing new therapies.

APIs. Their legal argument is that market exclusivity provided by a patent allows for research and development of the patented product but not its commercialization. Consequently, if a company wanted to develop the pharmaceutical technology required to produce the 600mg formulation of efavirenz, they would still require a CL to *purchase* the API. This key ingredient for making a medicine is also under patent!

In 2005, the last year of her administration at Farmanguinhos, Boechat (2008) said that she signed an agreement with Pedro Chequer to develop efavirenz, atazanavir, and lopinavir. The agreement included R$ 8 million in funding through Fiotec (the funding arm of the FioCruz foundation) for the purchase of raw material and development up to the industrial scale, but the main obstacle was obtaining APIs in to reverse engineer and develop the drug. Boechat explained:

> In 2005, there was a group at the National AIDS Program—including a group of lawyers contracted by them—and I was instructed to solicit a letter from suppliers for all purchases of raw materials. According to our law, they are obliged to sell to us. So I asked to purchase 200kg of evafirenz, 100kg of lopinavir, and other raw materials. They all refused to sell me raw materials, and only wanted to sell the finished product. According to the law, they have to sell. But since I had these letters, we opened the tender process to international companies. In 2005 Cristalia and some others entered the bidding process. The patent owners said that the law in Brazil permits purchases of raw materials, development of the product, and even registration but not commercialization. You need raw material in order to do the development and also to do the registration. The [patent owners] prohibited these companies to commercialize in Brazil.

Although Brazil's industrial property legislation allows for the commercialization of patented products for research and development (even without the patent holder's consent), foreign drug companies succeeded in filing court injunctions that circumscribed

FM's efforts to access active principals necessary for the development of new medicines.[60]

Other public labs faced similar obstacles when attempting to develop formulations of patented ARVs. Lafepe's development of new ARV formulations, despite the registration of 200mg efavirenz, remained problematic due to restricted access to APIs. In 2003-2004, the state lab was commemorating its entry into international markets after obtaining approval from the Pan American Health Organization for its pediatric formula of AZT.[61] In the following conversation, Rolim (2008), the former director of production at Lafepe, explains the difficulties related to sourcing active principals for developing patented medicines:

> Interviewer: Could you develop tenofovir?
>
> Rolim: We could develop tenofovir but it depends on the raw material. If I were to obtain the raw material, I would definitely work on it. I have all the interest to do so. I just need to get the raw material... Doing the API is very expensive. You need to buy all the intermediates and equipment. There are many stages.
>
> Interviewer: What about Kaletra (ritonavir-lopinavir)?
>
> Rolim: It was also part of our strategic plans, but the problem is access to raw material so we could not develop it. I need people, equipment and raw material.
>
> Interviewer: But you were able to some work on efavirenz?

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[60] Private generic drug companies do not face the same restrictions as public labs when taking advantage of the Bolar Exception. Since they are not required to publicize their tenders, patent holders do not have knowledge of their R&D strategies and therefore cannot lodge any injunctions restricting access to patented products.

[61] "We did do some donations of AZT syrup to other countries in Latin America and Africa. We were the only public lab that did AZT syrup. It was also important in confronting TNCs, which said that we did not have quality, at the moment when we started producing a lot of ARVs. They did not want us to start exporting to Asia and Africa at cheaper prices. All the TNCs with patents viewed Brazil as a competitor and wanted our product to just stay in Brazil. One impediment to exporting was the necessary registrations that we needed to have in that country. All these countries wanted to buy our product," said Rolim (2008).

> Rolim: I began working on it even when it had a patent because I got the raw material on the international market via donation. The supplier sends samples. Nelfinavir had a patent, but I developed it using samples from suppliers in India.

Interviews with the managers of other public labs said that patents are the main problem when attempting to develop patented medicines. They were able to circumvent this obstacle through donations provided by private sector companies. Since the product was *donated* and not *commercialized,* there was no legal impediment, but donations of APIs remained limited. Private domestic firms do not want to make a larger investment without a guaranteed market. Farmanguinhos was able to obtain some samples from Nortec, a Brazilian private pharmochemical maker and the lab's technological partner, but again, this option has its limitations.

Brazilian local ability to have generic copies of patented ARVs available for distribution in its AIDS program would comprise state autonomy during price talks in 2005. The challenge to surmount patent power would also present an opportunity for the powerful AIDS coalition to reach out to the pharmochemical industry.

US and NGO Pressures during Negotiations with Abbott

The year 2005 proved a pivotal one in Brazil's AIDS treatment program. ARV costs had jumped to R$ 1 billion, and 165,000 Brazilians were in treatment. Health Minister Humberto Costa demanded discounts and/or voluntary licenses from Merck for efavirenz, from Abbott for Kaletra (ritonavir/lopinavir), and from Gilead for tenofovir. Abbott was the most intransigent during the negotiations, and on June 24, 2005, Costa declared fixed-dose combination Kaletra to be in the public interest. The declaration is the first step for issuing a CL, and the patent holder would have ten business days to

respond. From 2002 to 2005, the number of patients using Kaletra jumped sevenfold to 23,400 and the annual expenditures reached $91.6 million. Health officials forecast that the number of patients would increase to 60,000 over the next four years. Negotiations with Abbott began in March, and negotiators demanded a price reduction from $1.17/pill to $0.68/pill—the cost that Farmanguinhos could allegedly produce the medicine. The talks with Abbott were complicated by the fact that Costa left office after supposedly reaching an agreement, and negotiations resumed under the new Minister Saraiva Felipe.

The Kaletra negotiations of 2005 illuminate the framing of interests, different alliances, and potential impacts that various groups have on the state as a result of globalization. Corporate defenders of strong intellectual property rights quickly began to lobby the USTR to apply pressure on Brazil in March soon after Humberto Costa had placed the CL option on the table. They couched their arguments in terms of stealing property and US national interests. "This theft has gone on at the expense of the American people and the US economy," said Nancie Marzulla, president of Defenders of Property Rights (2005). In this view, the victim is the US people who witness their intellectual creations suffer from Brazilian piracy. This frame captured the attention of members of the US Congress who lobbied the USTR to fight Brazilian "theft" and "piracy" of US intellectual property and questioned Brazil's "emergency" since its successful AIDS program kept prevalence rates comparable to those in the US (Wilson 2005). US legislators expressed concerns of national competitiveness being threatened by another rising economic power (Palmedo 2005):

> Brazil, with an economic output comparable to Germany, appears to be seeking a way to develop its generic manufacturing capacity through confiscating our pharmaceutical technology…Currently, Brazil is incapable of mass producing

> these medicines but could quickly become a generic provider by gaining American technology.

The concern was that Brazil would begin competing against US companies for export markets such as Africa. Indeed, Lafepe obtained quality approval from PAHO to export to Ecuador.

Transnational advocacy groups defending Brazil framed the issue not along nationalist lines, i.e. US versus Brazil, but in terms of greedy corporations. These activists claimed to push for the interests of people across the world (Health GAP 2005):

> Brazil has let itself be bullied by big drug companies long enough. It's time for Brazil to stand up to them and show the world the kind of global leadership this issue so desperately needs—Dr. Paul Zeitz, Executive Director of Global AIDS Alliance.
>
> The success of the Brazilian AIDS treatment program has been made possible by the local production of generic medicines. This policy has brought down the price of raw materials for antiretroviral medications internationally. The Health Ministry must stand up to pharmaceutical companies—not only for the Brazilian people, but for people living with AIDS around the world—Sean Barry of Health GAP.

The targets of malfeasance in this view are large corporations whose excessive prices keep access to drugs out of the hands of those who need them. Brazil's model AIDS program based on local production had become a symbol for the rest of the Global South. The Working Group on Intellectual Property, part of the Brazilian Network for the Integration of People [*Grupo de Trabalho sobre Propriedade Intelectual* – GTPI – *da Rede Brasileira pela Integração dos Povos* – Rebrip], organized worldwide petition drives through the internet, arguing that Brazilian officials were not assuming their leadership position at the WTO and other international bodies. By refusing to issue a CL,

they argued, Brazil was behaving like a "tiger without teeth." Activist efforts were capable of gaining the support of influential media such as the New York Times (New York Times 2005) that defended "Brazil's Right to Save Lives" in an editorial, but their efforts failed to win over US diplomats.

When Brazil first threatened a CL in 2001, US pressure consisted of a dispute resolution panel at the WTO. The US withdrew the panel after AIDS activists began to protest, and it became clear the legal basis of the complaint was weak. US authorities, however, retained other instruments of pressure. The USTR produces the annual "Special 301" Report that identifies countries that fail to improve the intellectual property protection.[62] If a USTR investigation discovers that a country is at fault, then trading privileges under the General System of Preferences (GSP) could be withdrawn.[63] In 2001, the agency placed Brazil on its Watch List and then on the Priority Watch List in 2003 after Brazil decreed the use of parallel imports in cases of a CL. During the Kaletra confrontation in 2005, members of the US Congress urged the USTR to withdraw Brazil's trade privileges provided under the GSP. Estimates of Brazilian exports affected by the possible trade retaliation range from $48 million (Boletín Farmacos 2005) to $3.6 billion (Kogan 2006).

A request made under the Freedom of Information Act (FOIA) of US Department of State Cables between 2004 and 2006 provide insight into the interactions between US

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62 The Special 301 provision is found in Section 182 of the Trade Act of 1974 and strengthened by Section 1303 of the Omnibus Trade and Competitiveness Act of 1998. Mandatory actions must be taken by the USTR according to a non-compliant country's classification. A "Priority Foreign Country" indication means that a country's policies or practices have the most adverse impact on US products; a "Priority Watch List" designation implies that a country has some but not all of the criteria for a "Priority Foreign Country"; and a "Watch List" classification mean that a country has some problematic IP-related issues (Sell 2003).

63 Sell (2003) has detailed PhRMA's influence on the USTR's decision-making process. Based solely on information provided by the lobbying group, USTR withdrew trade preferences worth US$260 million from Argentina in 1997 (Sell 2003:136). In the case of Brazil, PhRMA requested the USTR to include it on the Special 301 for lack of IP protection.

and Brazilian officials concerning the use of CLs.[64] The cables reveal the depth of US involvement in monitoring price negotiations, the politics of patents, and defense of US companies involved in the negotiations—Abbott, Merck, and Gilead. A cable dated June 3 from the American Embassy Brasilia (2005) with the subject heading "Ambassador Meets with US Pharmaceutical Firms Threatened with Licensing" makes the conclusion: "We continues (sic) to believe that to resonate with the [Government of Brazil], the arguments will need to provide a sound analysis as to why compulsory licensing would be damaging to Brazil's economic and public health interests." In subsequent cables, US diplomats warned Brazilian officials that a CL could harm the country's interests in attracting foreign investment and dissuade foreign drug companies to introduce new medicines into the market. US diplomats did not adopt the language of "piracy" or "theft" in their discussions that the defenders of strong IP protection employed, but the cables note that the Brazilian government invoked the "public interest" and not the "national emergency." In this way, Brazilian authorities could avert criticism that they were suffering from an out-of-control AIDS epidemic, since in fact their model program had kept prevalence rates at levels comparable to those in the US

The details provided under the FOIA request do not detail the full extent of US pressures since many sections in the cables were excised. Agenor Alvares (2008), who was second in command at the Ministry of Health under Saraiva Felipe and present during the negotiations, described the extent of US pressures:

> What was strange during the negotiations was the interference on behalf of the US Embassy. Diplomats from the US Embassy requested a meeting with us, and explicitly threatened that if a compulsory license is used the US would review all

[64] US-based consumer activist organization Knowledge Ecology International (KEI) published the cables on their website (2007).

> the partnerships between the US and Brazil, including training partnerships of Brazilians in research centers in the US. This was explicit. We took into consideration all the accords that Brazil and the interest of the Brazilian government to send Brazilian scientists to the US for training, we reaffirmed our intention that it is important for Brazil's technology development to continue sending scientists there, but we would not accept the threat.

It is amazing that US officials would make such an explicit threat to limit a country's technological development, but the action demonstrates how far US diplomats would go to defend the interests of its drug firms.

While direct threats did not convince officials from Brazil's Ministry of Health, it did lead to increasing intervention by other ministries in the topic. Both Alvares and Felipe said that the Minister of Development, Industry and Trade, Luiz Fernando Furlan, convened a meeting concerning the use of a CL in order to persuade health officials to find an alternative—an action outside of Furlan's ministerial jurisdiction. The fear of trade retaliation hit a nerve at the economic centers of Brazil's agro-export economy.[65]

The Brazilian government was feeling pressure not only from the US government but also from Brazilian civil society. On August 11, the National Health Council [*Conselho Nacional da Saúde—CNS*] approved a resolution recommending the immediate issue of a CL for Kaletra, efavirenz, and tenofovir "as well as other patented anti-retrovirals that burden or come to burden the budget of the Unified Health System—SUS". The CNS, which is composed of representatives from civil society, is the highest level of social participation in the country's health system. Although Saraiva Felipe as the Minister of Health is the president of the CNS and stated at the August meeting that "the

[65] More recently, Brazil threatened trade sanctions against the US after winning a WTO dispute over cotton subsidies. Before a bilateral settlement was reached, Brazilian diplomats threatened to suspend US intellectual property rights on seeds and medicines. "Traditionally, retaliation in trade has been the preserve of the largest developed countries, which have market power," said Robert Z. Lawrence, an economist at the Harvard Kennedy School. "But this mechanism — suspending intellectual property protection — gives smaller, developing countries a way to enforce their rights under trade rules" (Chan 2010).

only inviolable patent is that of life itself" (Boletín Farmacos 2005), he never signed the resolution and thereby never sanctioned its legal power.

When Felipe assumed command of the Ministry of Health on July 8, 2005, he attempted to depoliticize price negotiations. Agenor Alvares (2008), appointed second in command at the Ministry, explained that the first change the new minister initiated was to remove the "emotional weight of the negotiations and place the talks on a professional level." They assured US officials that the negotiation process would be transparent. However, leaders at the Ministry of Health had to contend with the AIDS coalition, which lobbied to "break patents" and who symbolized the "emotional weight" brought to bear on the administration.

The second change concerns the sources and uses of price parameters. When Costa led the negotiations, the target price was $0.68 per pill that Farmanguinhos could allegedly produce the medicine. That price dropped to $0.41 per pill after the New York Times (Prada 2005) quoted a Ministry Health official saying that an internal review of local producers demonstrated that they could provide the drug at the lower price. This price then became the new baseline that NGOs demanded and was mentioned in the CNS resolution. The new baseline appears more of a negotiating tactic than a definite reality, although US State Department cables relate that Brazil's Health officials said the Clinton Foundation could source efavirenz at the 41 cent price.

Despite the allegedly cheaper prices, the problems of sourcing Kaletra if a compulsory license were issued continued to haunt top officials. Jarbas Barbosa (2008), the Secretary of Health Surveillance involved in the negotiations, explained the difficulties in finding an alternative supplier to replace Abbott:

> At that moment, we did not have any generic producer of Kaletra pre-qualified by the WHO. We sent a mission to India, one person from the Ministry of Health and another from ANVISA, to have meetings with generic producers. They did not have the product in stock and affirmed that they could make it, but we would still have to carry out bio-equivalence and bio-availability tests. This had a major weight in our decision in not issuing a compulsory license…In relation to national production, we did not have any producer of the basic salt [the API] for Kaletra. There was the possibility of an Indian producer supplying the basic salt to Farmanguinhos, but then we would still have the same problem. There was no Indian producer of the basic salt pre-qualified by the WHO…Farmanguinhos still could have used an Indian supplier of the API, but it still would have taken two years to complete the development. We did not divulge this because it would have weakened our bargaining position.

Since no producer had completed the quality tests, health officials worried that doctors would not prescribe the medication to their patients. Barbosa explained that Abbott eventually offered a price below that of Indian producers. The final agreement signed on October 10th cut the price of Kaletra to $0.63/pill (the lowest price for the ARV outside of Africa).

AIDS bureaucrats and their NGO partners were outraged by the accord and kept up the pressure. One of their chief complaints was that the contract was valid until 2011 and did not foresee the possibility of future price reductions or technology transfer. On December 1st, World AIDS Day, activists filed a civil lawsuit requesting an injunction against the contract signed with Abbott and an immediate compulsory license for the drug. Pedro Chequer (2008), the director of NAP, said that he provided all the necessary information to NGOs to carry out legal actions, but the courts did not uphold the injunction, arguing that a CL would harm the country's economic interest due to possible US retaliation. More importantly, the court questioned whether there was technical proof of the country's local capacity to produce the medicine at $0.41.

The Kaletra episode was a humbling experience for Brazil's AIDS coalition. It revealed the limits their actions could have on pressuring for certain outcomes. Their power remained limited to the degree that there are readily available alternatives to source ARVs. But the confrontation with Abbot also provided a political opportunity for this dual coalition of "social movement insiders" and outside activists to develop closer ties with the country's local pharmaceutical sector.

Representatives from Brazil's private sector drug companies said that Chequer actively sought companies that could provide the key inputs to Brazil's public labs. During the negotiations, the Brazilian Fine Chemical Industry Association (*Associação Brasileiro das Indústrias de Química Fina, Biotecnologia e suas Especialidades*—Abifina), the most vocal of the private sector lobbying groups representing domestic companies, did not make any declarations in favor or against the use of a CL for Kaletra, but the entity and its members did provide health officials with information about the sector's capabilities.[66]

A number of organizations outside of government also began to carry out evaluations of Brazil's pharmaceutical capacities, including the Clinton Foundation (2006) and the United Nations Development Program (UNDP 2006). Besides these important studies, Doctors Without Borders teamed up with ABIA (Fortunak and Otavio Antunes 2006) to finance a study of Brazil's local production capabilities. At this point, activist groups were becoming directly involved in industrial policies and establishing closer ties to the domestic pharmaceutical sector. The timing could not have been more

[66] Alvares (2008) said that Cristalia could offer the API to Farmanguinhos at a price of R$ 0.47 per pill, about US$0.20. Farmanguinhos, in turn, said they could have the final product available in two year's time as long as there were no problems at any stage of development. Here again, there remains the problem of the time-delay between having a readily available alternative in case a CL is issued and the time necessary to complete a drug's development and certification.

auspicious since the government of Lula began to implement industrial policies to support the pharmaceutical sector.

CHAPTER SUMMARY

The 2002 to 2005 period that overlaps Lula's first term in office marked the nadir of state autonomy in the country's AIDS program. As predicted by theories of globalization, the impact of patent power constrained the policy space available to politicians. Had Brazil not incorporated TRIPS into its legislation, dependency could have been averted. Market power from increasing Indian and Chinese competition would continue even without TRIPS, especially if the pharmaceutical sector did not receive government support in the form of industrial policies. External factors were not the sole reason for weakening domestic capabilities, for lack of government coordination and restrictive domestic regulation also played their part; weakened state capabilities stymied the AIDS coalition to take full advantage of Brazil's "reputational dividends." The episode, however, provided an opportunity for another key ally in Brazil's fight against AIDS—the domestic pharmochemical sector.

In the next chapter, I explain the Brazilian government's *dirigiste,* or state-directed, approach to developing domestic pharmaceutical capabilities through the implementation of a number of industrial policies for the sector. Most importantly, in 2007, Brazil decided to issue a compulsory license for Merck's efavirenz. The action symbolized the institutionalization of the *triple alliance* between social movement insiders, human rights activists, and the private domestic drug industry.

CHAPTER FIVE – CONSOLIDATION OF THE DOMESTIC TRIPLE ALLIANCE (2006-2009)

Here in Brazil it all ends up working out, but very slowly. It could be much better.

—Lelio Maçiara, chemical engineer and drug maker

This chapter will explain the development of industrial policies for Brazil's pharmaceutical sector. Essential drugs and medicines used in the country's public health system (*Sistema Unica da Saúde*—SUS) are increasingly defined as "strategic" goods. The Brazilian state, led by its Ministry of Health, took an increasingly *dirigiste* role in directing the development of the health industrial complex. Through public labs such as Farmanguinhos, the Ministry established public-private partnerships with local pharmaceutical companies in order to nationalize the production of strategic medicines. These initiatives solidified the support of important sectors of the national bourgeoisie for the country's aggressive AIDS policies. At the same time, industrial policies increased the distance between the state and transnational drug companies.

The institutionalization of this domestic *triple alliance* organized by civil servants in the Ministry of Health thus provided the social bases for government use of the flexibilities outlined in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). This is evident in the cases of two important anti-retroviral medicines (ARVs), efavirenz and tenofovir. After several episodes of contentious price negotiations and threats over the use of compulsory licenses (CLs), Brazil finally issued a compulsory license in 2007 for Merck's efavirenz. By this time, members of the triple alliance assumed concrete roles to support the decision.

IMPLEMENTING INDUSTRIAL POLICIES

Technological Transfer and Lead Up to Public-Private Partnerships

Developing countries viewed technology transfer[67] as part of the deal when they signed on to TRIPS. Attempts to create working groups and consultation systems at the intergovernmental level for resolving issues related to technological transfer have only revealed the discrepancies between developed and developing countries (South Centre 2005). Brazil's experiences in requesting technology transfer of AIDS medicines from patent holders reveal the strategic nature of pharmaceutical technology and increasing divergences between the interests of transnational drug companies and developing countries.[68]

During price talks with transnational drug companies, Brazilian negotiators always requested a voluntary license. On no occasion did these negotiations result in a patent holder agreeing to transfer technology to the Brazilian public or to private labs. Discussions advanced the furthest in the case of Merck's efavirenz, but Brazilian officials rejected company proposals. In the view of the Brazilian government, the transfer was only to be concluded two years before the patent's expiration on 2012 and with the condition that the active principal ingredient was provided by the company.

In lieu of voluntary licenses, Brazilian policy makers have taken a *dirigiste* approach towards acquiring technology. The previous chapter showed that

[67] Technology transfer is defined as "transfer of systematic knowledge for manufacture of a product, for the application of a process or for the rendering of a service" (Chapter 1: 1-2 of the Draft International Code of Conduct on the Transfer of Technology).

[68] The Brazilian government and transnational drug companies have achieved a limited number of partnerships in developing health technologies, most notably in the area of vaccines. FioCruz has joint projects with GlaxoSmithKline, and the Butanta Institute, another government research institute, has partnerships with Sanofi Pasteur.

pharmochemical production remained the Achilles' heel of Brazilian local production. Not only have patent holders restricted access to APIs, but on several occasions the poor quality of imported raw material increased costs and delayed production, often times forcing the National AIDS Program to ration treatments. With the public labs monopolizing end production of ARVs and the Ministry of Health establishing state enterprises in other product lines,[69] why did the Brazilian government not just establish its own pharmochemical company?

Managers of public labs expressed the need for a stronger pharmochemical industry but also had mixed opinions concerning the best course of action. Eloan Pinheiro (2008) said she was against the idea of Farmanguinhos (FM) having its own API manufacturing plant due to public sector inefficiencies. Nubia Boechat, who succeeded Pinheiro at the federal lab, had a different view. In fact, during her administration Farmanguinhos (FM) purchased a production facility from GlaxoSmithKline for R$ 18 million (about $9 million) to increase capacity to over 10 billion units. The purchase, however, did not include a pharmochemical division. Boechat (2008) still wanted to expand into upstream production:

> I wanted to purchase a pharmochemical factory to do FM's raw material. If I would have stayed in the administration, that is what I would have done. I wanted to get Microbiologica's old factory to produce on an industrial scale. I would have invested in this. We were pretty advanced in the negotiations. I come from the API sector and would have invested in this. I do not agree with the policies of [current FM's director] Eduardo Costa who believes that we should support national private API manufacturers. FM's market is completely different from the private market. But even if we had purchased the API manufacturing plant, I think

[69] The Ministry of Health, seeing a gap in the local production of Factor 8 and 9 as well as immunoglobulin, decided in 2004 to invest US $60 million to create a company called Hemobrás and purchased the requisite technology from the French state-owned company *Laboratoire français du fractionnement et des biotechnologies* (LFB).

> we would have done the same modality of out-sourcing the API in the case of efavirenz to national producers or Indian companies. I don't think it would have been much different. But with the Indians under TRIPs, it will become increasingly difficult.

The purchase of the API plant never came to fruition. Had the state invested in an upstream factory, it is unlikely that it would have had an impact on producing efavirenz before the compulsory license for the drug. Instead, policy makers have embarked on various public-private partnerships to develop APIs and medicines.[70] With India adhering to TRIPS in 2005, the need for developing local API capabilities became increasingly more important. Patent barriers could restrict the future sourcing of both medicines and active principals from Asian countries.

Need for Industrial Policies to support the Pharmaceutical Sector

Brazil's 2005 price dispute with Abbott revealed the need for a strong pharmaceutical base to support its AIDS program, and local industry was keen on obtaining a cut of the government's R$ 1 billion in annual ARV purchases. Industrial policies were needed to support the beleaguered sector. By the turn of the century, neoliberal ideology amongst policy makers began to give way towards more of an interventionist attitude. Although economic policy making remained in the hands of orthodox economists like Pedro Malan, Health Minister Jose Serra favored state promotion of national development goals. He was instrumental in passing the Law of Generics in 1999, which stimulated the development of a national generic drug industry,

[70] One exception to the state not entering the API business is a pharmochemical hub being established in Pernambuco. Hemobrás will also include a space for Lafepe's upstream activities (Rolim 2008).

but the bill benefitted more end product producers than the pharmochemical sector responsible for the production of active principals (Brasil 2008b). Nonetheless, towards the end of Cardoso's presidency, nonetheless, new sector funds were set up to stimulate technology in local industry, including the Health Sector Fund (*CT-Saúde).* This program was established to encourage private investment in research and development for products destined for the public health sector.

The National AIDS Program was also pushing the government to support the pharmaceutical sector to ensure the long-term sustainability of its treatment program and to improve its bargaining leverage in ARV price negotiations. By the time Alexander Grangeiro left the program in 2003, the link between compulsory licenses and industrial policies had become more obvious, but one had to come before the other. Grangeiro (2008) explains:

> [the] compulsory license is not a solution for the pharmochemical sector. The whole compulsory license process is so exhausting; to base development policy on a compulsory license is not reasonable. Better to strengthen the technical capacity of the industry which gives you a lot more power to regulate prices. Having the technical capacity and having the medicines on the shelves already facilitates price regulation. The other initiative is to provide investment so industry could work on small innovations and improvements of the medicines. We discussed with [national development bank] BNDES the possibility of providing incentives to this area and to ARVs…

Compulsory licenses, given their political and bureaucratic complexity, should not be seen as a form of industrial policy.[71] With the arrival of Luiz Inacio 'Lula' da Silva to

[71] This counters claims by US-based groups that Brazil was trying to become an export platform in medicines made with US knowhow.

power in 2003, Grangeiro and others found a more receptive government in relation to industrial policies.

The Workers' Party headed by Lula had been currying favor with Brazilian industrialists during its presidential bid. The new administration now had a chance to deliver.[72] *Guidelines for Industrial, Technological, and Trade Policies* (Brazil 2003) outlines the vision of the new government to provide support for domestic industry. Its conclusions were drawn from increasing debate and policy recommendations concerning the fragilities of Brazil's pharmaceutical sector that had increased since the turn of the century (Marília Bernandes Marques 2002; Palmeira and Pan 2003; Palmeiro Filho and L. X. Capanema 2004; Ministry of Health 2003). Given the sector's high levels of R&D, looming trade deficits, and the tie-in to public health objectives, drugs and medicines were considered a strategic sector for government support, alongside semiconductors, software, and capital goods.

Industrial policies for the pharmaceutical sector got off to a slow start during Lula's first term in office. The one exception is the *Profarma* program administered by Brazil's National Development Bank for Economic and Social Development (*Banco Nacional de Desenvolvimento Econômico e Social*—BNDES). The program's objective was to strengthen local industry by upgrading facilities to stricter quality and regulatory standards (such as the Good Manufacturing Standards), expanding their production portfolios, and even encouraging domestic mergers and acquisitions. BNDES program managers Palmeiro and Capanema (2005) responsible for Profarma explained the increasing strategic nature of medicines:

[72] He also wanted to use state power to support the growth of Brazilian multinational corporations (see Flynn 2007).

> Medicine is not the same as any other product. It is strategic. You can't remain exclusively in the hands of commercial relations. If there were a war for example between India and China, you must have capacity to produce locally…another possibility is if the US were to take action against India or China at the WTO for a certain product…

BNDES officers underscore the increasing importance Brazil's top policy makers give to addressing the country's growing dependency on pharmaceutical imports.

During Lula's second mandate (2007-2010), policies for supporting the pharmaceutical sector became increasingly concentrated in the Ministry of Health instead of in the Ministry of Development, Industry, and Foreign Trade. Jose Temporão, who assumed command of the Ministry of Health in March 2007, centralized health-related industrial policies in the Secretariat of Science, Technology, and Strategic Inputs under the rubric of the Health Industrial Complex.[73] The Secretariat coordinated with other government agencies and programs to encourage import substitution and new innovations to feed the needs of the public health system (SUS).

The Health Industrial Complex specifically mentions the "structuring of public production and transfer of technology of strategic pharmochemicals to the country, including the nationalization of anti-retrovirals" (Ministry of Health 2008b: 47). For state officials interested in stimulating the pharmochemical industry, this means conducting as many stages of synthesis locally, especially the last steps of synthesizing the API.[74] To

[73] "It all crystallized in the second half of Lula's mandate…Temporão does not present a political party but that of a physician, sanitarista, with a national program in line with all the ideas that ABIFINA has been defending," explained Brasil (2008).

[74] "Verticalizing all the production of APIs here is nearly impossible today, but the more stages of synthesis done here, the better. What is most desirable is that the last steps of the API are done here. The problem with the entire route of synthesis is that the Chinese dominate the intermediate market. Setting up the entire intermediate industry here would be very expensive and involve lots of pollution," said Andre Porto (2008).

this end, the Health Ministry has drawn up a list of "strategic medicines" that includes, among others, all the ARVs used in the national treatment program.

Brazil's industrial policies for the pharmaceutical sector represent a coup for the Brazilian Fine Chemicals Producers Association (*Associação Brasileira das Indústrias de Química Fina*—ABIFINA). During the Lula government, the industry association has achieved an important space in the policymaking process due to shared interest with state elites in developing local capabilities to supply the growing demands of SUS. The director of Farmanguinhos even gained a seat on the association's board.

The distance between the Brazilian government and transnational drug companies, meanwhile, has grown during Lula's second term in office. For Jorge Raimundo (2008), president of the consultative committee of INTERFARMA, the close working relationship with Fernando Furlan at the Ministry of Development, Industry, and Trade came undone in Lula's second term.

> With Furlan, we were able to advance in the areas intellectual property, investments, support for foreign companies to invest in Brazil and to have financing from the BNDES, improving ANVISA's flexibility, and recognizing and incorporating new technology, access to medicines, reducing the arm of the state in the production of drugs, use the state's money to equip hospitals instead of constructing factories. Now all has changed and we have the health industrial complex, factory investments...It is the same government that lets the hospitals deteriorate, and they want an industrial complex.

For Raimundo and other representatives of foreign industry (Singer 2007), the government should restrict its role to issues of access through targeted social policies and private insurance coverage for drugs whereas producing medicines should be left to the private sector.

Representatives from local divisions of foreign drug companies have expressed their attraction to aspects of the industrial policies—but with reservations. João Sanches (2008) who was in charge of government affairs at the Brazilian division of Merck, explained:

> In the program, there is what they call the pharmaceutical or health care value-added chain, which includes the pharmaceutical sector. These include strategic products for [the public health system]. What strategic means is different for different people. But what they say that is strategic is that Brazil can't be dependent on international sources of supply. Sometimes we see this as nationalistic...

The Lula administration represents an important shift in ideology compared to the previous Cardoso administration. While the Workers' Party has not rescinded past neoliberal policies, it has charted a new direction towards developing local industrial capacity in a globalizing world.

The actors involved in devising the industrial policies reveal the state's increasing embeddedness with national industrialists. Andre Porto (2008), a project coordinator from the Ministry of Health, who participated in reforming government policies and defining the strategic objectives, explained:

> INTERFARMA did not participate in the development of the new industrial policies. It was more ABIFINA and ABIQUIF that contributed. NGOs did not. One TNC informally said that they could do technology transfer and even said they could do all the strategic medicines. But that is not our intention to foment the development of local industry and then just kill it, which would be the case. The TNC wanted to have a market guarantee by the government…AIDS of course has been an important motivation for the new industrial policies.

Neither civil society groups nor INTERFARMA, which represented transnational drug companies, played important roles in contributing to the new policies. Instead, industry associations representing the national bourgeoisie have taken the lead.

While civil society groups did not participate in discussions about industrial policies for the health sector, they continued to defend initiatives focusing on local production. Veriano Terto (2005) explains the position of AIDS activist group ABIA:

> For ABIA, it is a concern that being merely a country that consumes ARVs and not produces them could threaten Brazil's program since more and more resources will be needed. Thus, ABIA defends industrial policies in relation to medicines to ensure the country's autonomy. One of the principles of TRIPS is to transfer technology, but this is not the case. Big Pharma argues that it can't share its industrial secrets and that it is more important to keep people alive by using its products.

Civil society groups have taken a growing interest in the challenges and obstacles faced by local industry to provide strategic medicines. The connection between industry and civil society, however, remains the weakest link in Brazil's triple alliance against corporate globalization. AIDS activists are distrustful of profiteering by private industry. Nonetheless, AIDS activists have grown more aware of the difficulties related to local production. Mario Scheffer (2008) from Grupo Pella Vida explained: "We never had direct dialogue with industry. Now we are coming to understand the position of private industry here. For example: their reluctance to invest in producing ARVs if preference is given to buying from public labs. This is the reality."

The most important change affecting the construction of Brazil's triple alliance was the decision to establish partnerships between public labs and private API manufacturers for the production of active principals used in AIDS medicines. When

Eduardo Costa assumed command of the Health Ministry's public lab Farmanguinhos (FM) in February 2006 from Nubia Boechat, he introduced a new mode for acquiring APIs. Instead of carrying out auctions that award contracts to the lowest bidder, the lab sub-contracted out API production to pre-qualified domestic producers.

Importers took FM to court for allegedly contravening the country's rigid Law on Public Tenders (*Lei de Licitação 8.666 de 1993*), but FM's lawyers made a convincing argument that the new modality for acquiring the API actually economizes resources, since its technicians could monitor the production process and guarantee quality and technical specifications.[75] ARVs were the first product line to use the new modality (Costa 2009).

Industrial polices during the Lula administration enshrined the support of local industrialists and boosted state autonomy. Headed by *sanitaristas* with a nationalist bias, the Ministry of Health has been at the center of constructing the triple alliance with advocacy groups on the one hand and local bourgeoisie on the other. Now the government was in a stronger position to confront foreign drug companies.

COMPULSORY LICENSE AND DOMESTIC COALITIONS

The Decision to Issue a Compulsory License for Merck's Efavirenz

[75] Sub-contracting production services of APIs also overcame another contradiction in Brazil's complex regulatory framework governing pharmaceuticals. The Law of Generics stipulates that drug makers must retain three API producers in order to obtain generic certification of their product. Since public labs had to award contracts to the lowest priced seller, typically on a yearly basis, they often had only one supplier of raw material, which could change from year to year. Consequently, their products retained the denomination of *similar* as opposed to *generic*. While a *similar* and *generic* may have the same API, quality assurance is greater for *generics* since they pass through bioequivalence and bioavailability tests.

In May 2007, Jose Temporão, Brazil's Minister of Health (2007-present) finally made good on Brazil's threats to 'break the patents' of drugs used in its AIDS program. The minister said that Brazil issued the compulsory license (CL) for efevirenz because US-based MerckSharpeDohme (Merck) did not reduce the drug's price low enough to fit within the Ministry's budget parameters. Brazil requested Merck reduce unit prices from $1.65 to the price of $0.65 enjoyed by Thailand. Since Brazil purchases larger quantities of the AIDS' medicine, Brazilian negotiators argued, they should receive at least a comparable price.

Merck's formula for pricing AIDS medicines, however, is based on a country's level of development and HIV prevalence rates, of which Thailand's is three times greater than Brazil. Merck initially provided a discount of 5%, which increased to 30% in its last proposal, thus effectively reducing the unit price to $1.10. The company also offered to transfer technology to produce efavirenz, but for Brazilian officials the price discount was not steep enough and offers of technology transfer not in line with the country's strategic objectives (see above).

After nine rounds of negotiations and stocks of the medicine decreasing, Brazil's government declared efavirenz in the public interest, and on May 5, 2007, President Luiz Inacio 'Lula' da Silva announced the compulsory license. It appears ironic that Brazil's president transformed the occasion into a media event that Minister Temporão could have conducted behind closed doors. Would US' President George W. Bush have done the same if the US issued a compulsory license for ciproflaxin in the wake of the anthrax attacks of 2001? It is unlikely. For Brazil, the "reputational dividends" of its AIDS program reach up to the highest office.

As a result of the CL for efavirenz, Brazil expects to save US$30 million in 2007 and a total of $236.8 million by the time the patent expires in 2012 (Ministry of Health

2007). Some 75,000 of the 180,000 patients in Brazil's treatment program were using the ARV in 2007. The CL had important knock-off effects in other negotiations, too. Brazil obtained price discounts it sought in subsequent negotiations with Abbott for Kaletra (lopinavir/ritonavir) and Gilead Sciences for tenofovir.

A number of factors had changed leading up to the CL compared to previous threats. First, the availability of WHO pre-qualified generic versions of the medicine was pivotal in providing an alternative supply of the strategic medicines in a short time horizon. In fact, initial purchases of the medicine came from three Indian companies pre-qualified by the World Health Organization (WHO) for $0.45/unit until public labs scaled-up production.

In the past, local producers, both government labs and private national companies, had provided input on costs. Knowing that Farmanguinhos provided support during the negotiations may have led patent holders to concede to government demands for a price discount in the past. On the one hand, the inability of Brazil's public labs to take advantage of the Bolar Exception (i.e. develop a drug and obtain regulatory approval for marketing before its patent expires) as noted in the previous chapter improved Merck's bargaining position. But on the other, the availability of generic alternatives certified by inter-governmental organizations weakened the firm's negotiating strategy and provided Brazilian health officials ammunition against criticism related to the quality of generic medicines.

A second important difference between previous threats and the CL for efavirenz is that other sectors of the government backed the Ministry of Health. During the 2005 negotiations with Abbott, ministries related to trade and finance voiced concerns about the possible ramifications of trade sanctions were Brazil to issue a CL for Kaletra. Two

years later the situation had changed—all the other ministries supported health officials' tough stance against Merck (Passarelli 2007).

One factor is the recent changes in ministers. João Sanches (2008), Merck's communication's director, explained: "The problem was we had a new cabinet, a new Minister of Health and a new Minister of Commerce. And we, Merck, did not even have time to talk with these ministers because they had changed so quickly." Merck officials did not have time to curry favor with strategically placed officials in the Lula government and entice them with prospective investment plans. Another related factor is derived from the concept of "cognitive liberation" from social movement literature (cf. McAdam 1982). Policy makers had finally overcome the fear of retaliation and the belief that the CL was like an "atomic bomb" to be used in the last instance.

Part of overcoming the fear of political backlash and obtaining increased ministerial coherence stems from a third factor—less direct US pressure during negotiations. During previous threats of a CL, there had been parallel pressures of a trade panel at the World Trade Organization and overt threats of restricting US science and technological partnerships. In a review of US government documents related to the CL (obtained under the Freedom of Information Act), US diplomats repeated the common theme of the importance of patents for generating new innovations. US officials did not express any outright threats or present challenges at international bodies during the efavirenz negotiations. If Brazil was going to break Merck's patent, the US ambassador only warned the Health Minister that there would be a "political storm" (Mazurkevich 2007).

Brazilians involved in the negotiations and interviewed for this research also did not mention any US pressures. In fact, the US Trade Representative (USTR 2007) had removed Brazil from its Priority Watch list due to the country's efforts to protect

intellectual property, although it continued to highlight concern over the use of CLs. The US also did not apply any trade sanctions nor initiate any out-of-cycle reviews of Brazil's intellectual property protection, despite pressures from the Pharmaceutical Research and Manufacturers of America (PhRMA).[76]

Industry and their supporters continue to stress the importance of strong patent laws. Certain groups such as USA for Innovation (2007) called on the US Congress to fight Brazil and Thailand's "theft". But this language is not employed by the rest of industry. The mainstream view from industry alleges that it is not against CLs per se. Instead of invoking terms such as "theft" and "piracy", industry representatives argue that Brazil's effective treatment program would not be possible without innovations carried out in the private sector that result from strong IP protection.

A PhRMA representative said that the Brazilian government acted within the TRIPS agreement but "against the spirit of the law" when issuing the CL (Singer 2007). Representatives of the Brazil's pharmaceutical industry dispute the "public use" justification. Ciro Mortella (2008), executive director of the Brazilian Pharmaceutical Industrial Federation (*Federação Brasileira da Indústria Farmacêutica*—Febrafarma), an umbrella organization that includes both foreign and domestic companies, explained:

> The compulsory license is proscribed in the law, but it is not proscribed in the law that its use is justified to achieve economic savings. What justifies a compulsory license is public utility…Economic savings and public administration was not considered in the spirit of the law in intellectual property. When you talk of public

[76] US actions in the Brazil case suggest that direct US support to industry in cases of compulsory license has decreased since Thailand issued compulsory licenses for medicines in late 2006 and early 2007. Several international civil society organizations criticized the US for pressuring Thailand after the Asian country issued several compulsory licenses. After this episode, the US has not made taken any explicit actions against countries that opted for CLs. Instead of applying pressure in specific cases, US efforts in stronger IP protection focus on trade talks and international treaties.

> interest in the law, you are talking about an exceptional situation, a situation outside the normal such as September 11th.

Industry representatives thus have a definite normative view considering the use of CLs apart from strict legal definitions. However, this view carries few allies within the Brazilian state health complex given their emphasis on "strategic medicines," nor with the access to medicines movement.[77]

Merck's discourse has also adjusted to the changing counters of Brazilian politics and use of CLs. While the company viewed itself as the "victim" when efavirenz's market exclusivity was revoked, the company's discourse also invoked ideas of partnership in the country's economic development. Sanches (2008) from Merck explains:

> Let me make this clear. Merck is not against the use of CL. This is in every country's regulations and laws. We argue against the government's reasons. Public interest is not just budget concerns. What about other public's interest in exports, R&D, jobs, and bringing innovation to Brazil?

The director informed that, besides offers to transfer production and technology related to efavirenz, its CEO, Richard Clark had discussed with Brazil's President Lula the firm's investment plans for establishing an innovation hub in the biotech and life sciences in Brazil. But after the CL, Tadeu Alves, the president of Merck's Latin American division, said that "the perception of Brazil will not be the same" and that the company is reviewing its investment plans in the country (Borsato 2007).

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[77] One notable and vocal exception is the Brazilian-American Chamber of Commerce. The biggest opposition from industry comes from those sectors with commercial relations with the United States, including Brazil's powerful export agricultural sector.

Merck's investment offers came too late and won too few supporters. Even Miguel Jorge, the new Minister of Development, Industry, and Trade, acknowledged that Brazil was only saving a minor amount by relying on the CL compared to the possible impact on future investment. Nonetheless, he said that Merck "precipitated this situation" and other ministries supported the policy (US Embassy Brasilia 2007).

For Brazilian health authorities, Merck's actions, far from transferring technology to develop Brazil, have kept the country from developing an important technology. Eduardo Costa (2009), the director of Farmanguinhos at the time of negotiations, insisted that one of the factors that contributed to the government's decision to issue a CL was the company's court injunctions limiting access to the active principal ingredient of efavirenz.

The testimonial from Agenor Alvares (2008), the adjunct Minister of Health at the time, is the most illuminating in this regard. Since he was involved in two important negotiations—the Abbott confrontation in 2005 resulting in a negotiated settlement and the Merck talks leading up to the CL—his perspective is insightful of the companieis' two different approaches and respective outcomes:

> The first accord that Merck presented was completely unfeasible for the Brazilian government. They presented a timeframe for completing the transfer of technology when the patent had expired. So we told them that this was not interesting and that we would like a different price from 2006 onward. They returned in 2006, and we initiated a discussion that was the most difficult because Merck basically sat at the table to play poker. They basically thought that the Brazilian government was bluffing in terms of using a compulsory license. They thought that our poker hand was weak, but we did not have a weak hand. We had the support of the presidency and all the bodies of government. All the price offers that they made throughout the year of 2006 and up to the beginning of 2007 were unacceptable…So we began to organize ourselves internally and seek support from other branches of government.

Alvares and other government officials can relate the reasons and events leading up to the CL, but fundamental in supporting the government's move has been the institutionalization of alliances made between civil servants at the Ministry of Health, civil society activists, and private domestic drug makers.

The Consolidation of the Domestic *Triple Alliance*

Each time the government considered issuing a compulsory license and took the first step towards that end by declaring a specific medicine in the 'public interest' a political opportunity was created that resulted in increased societal mobilization. The two pillars of support for government initiatives for using TRIPS-related flexibilities are civil society organizations and the domestic pharmaceutical industry. The positive outcome of each failed attempt of using a CL has been the establishment of stronger relationships between the Ministry of Health and these two groups. The increasing politicization over the issue of patents has concatenated into a formidable triple alliance.

In the original formulation of this concept developed by Evans (1979), the triple alliance was a key component in explaining dependent development. It was comprised of state bureaucrats, transnational capital, and the domestic bourgeoisie. The unforeseen consequence of globalization thirty years later is the severance of TNCs and incorporation of civil society groups tied into transnational networks of activists. My argument is that activist bureaucrats, acting as social movement insiders, in the Ministry of Health have been at the center of constructing this triple alliance.[78] Evans (1996: 1119)

[78] The argument that Brazil's social movement built around AIDS has been the catalyst of change and thus explains the development outcomes is limited by the case of Kaletra described in Chapter Four. Another

has employed the term *synergy*, to describe the "mutually reinforcing relations between government and groups of engaged citizens." However, the evidence provided so far suggests that the construction of synergistic relations has been highly political, as suggested by Hickey and Mohan (2005).

By the time Brazil finally issued a CL in 2007, the triple alliance was consolidated and concrete roles played by domestic private industry and advocacy groups established. In fact, several observers were surprised by the decree. Maçiara (2007) from the pharmochemical industry explained that previous health ministers when confronting TNCs had always consulted with the makers of active principal ingredients, but Minister Temporão did not.[79] Members of Brazil's domestic API industry tend not to lobby the government to use CLs, but remain important defenders of Brazilian policies in this regard. Nelson Brasil (2008b), Vice President of Brazilian Fine Chemicals Industry Association (ABIFINA) explained:

> The compulsory license will not affect the growth of the API manufacturing industry. The compulsory license for efavirenz was absolutely legal and legitimate. The use of the compulsory license is not unrestricted and should not be…The US on a daily basis even kidnaps intellectual property, not in the name of health, but more so in the name of defense or economic abuse by removing concessions in cases of anti-trust law. In Brazil, the use of compulsory license is for anti-trust purposes or for 'public interest,' and it has to be used. It should be used soberly.

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argument, and an detailed in Chapter Two, is that government and social movements fused during the 1980s and 1990s when developing Brazil's National AIDS program.

[79] "Temporão never consulted us much and just decided to break the patent. The other times they consulted us a lot. It was a surprise. He could have done it in a different fashion. We could have prepared ourselves a little more," said Maçiara (2007), referring the import of the drug in lieu of the domestic industry not having the drug readily available.

The discourses of Brasil and Maçiara represent the nationalist viewpoint of domestic industry. Had the country's pharmaceutical sector been more fully integrated into global circuits of capital through trade relations or mergers and acquisitions with larger TNCs, they would likely take a different position.

When comparing the evolution of IP legislation between Mexico and Brazil, Shadlen (2009) correctly argues that Mexico incorporated fewer TRIPS flexibilities since Mexico's generic pharmaceutical industry is more closely tied to the US market and enjoys higher levels of foreign ownership. Despite the early passage of TRIPS, Brazil incorporated more TRIPS flexibilities at a later date because of the interests of a nationally owned pharmaceutical base. Shadlen (2009) highlights the role of industry association ABIFINA in promoting more flexible intellectual property legislation. What is missing in his analysis of the Brazil case is the strategic role played by pro-active public health officials to promote changes in intellectual property laws and industrial policies.

In Brazil, the Ministry of Health through its many affiliated organizations has played a leading role in pushing for industrial policies to develop the country's pharmaceutical industry. The most important policy for obtaining the support of national capital was FM's decision to sub-contract API production to domestic producers instead of holding tenders. The new public-private partnership, along with several industrial policies, solidified the support of the domestic pharmaceutical industry, especially the weakest link in the production chain—the pharmochemical producers.

The relationships between the Ministry of Health and civil society organizations developed along a different trajectory. The key intersection between the ministry and social movements has been the National AIDS Program (NAP). Nunn (2007) recounts how the body responsible for developing and implementing policies to deal with the

epidemic recruited heavily from activist NGOs. This mobilizing structure continued in relation to the issue of intellectual property and access to medicines.

During the 1990s, public health reformers failed to stop the passage of intellectual property legislation that would affect access to medicines, due in part to their weak links to strategic allies in other civil society. At the time, the pharmaceutical sector, especially pharmochemical makers, were grappling with neoliberal reforms that removed protectionist barriers and eliminated industrial policies. AIDS activists were not cognizant of the impact patent laws would have on drug prices until the use of patented ARVs became more widespread and Minister Serra began to confront the US over TRIPS. One AIDS activist[80] explained in a personal interview:

> We were somewhat aware of patent laws when they were passed in 1996. But we really began to see the impact when the US set up the panel at the WTO. We demonstrated in front of the US consulate and in Recife during an AIDS conference. We had more of the initiative and took the problem to government officials.

In the view of the activist, social movements made government officials aware of the situation. But it was the WTO dispute of 2000-2001 that galvanized activists to mobilize on issues of intellectual property.

While AIDS activists have been pivotal since the 1990s in pressuring government officials to confront TNCs and "break patents", more interesting from a resource mobilization perspective was the need for increasing technical competence in the area of pharmaceuticals and IP law. São Paulo-based activist Mario Scheffer (2008) explained:

[80] The interviewee preferred to remain anonymous.

> We have accumulated a lot of experience. Negotiations and treatments have always been a very complex topic. Within the priorities of the movement it was not preferred due to the technical level required and also due to interest.

Many workers and volunteers at activist NGOs prefer to work on concrete issues and face-to-face care provision instead of sorting out the technical details related to patents and pharmaceuticals.

The professionalism within and coordination between NGOs evolved over time to act as interlocutors with the government and explain the issues to a wider audience. The new organization created to lobby the government on patents and access to medicines is the Working Group on Intellectual Property from the Brazilian Network of Peoples Integration (*Grupo de Trabalho em Propriedade Intelectual da Rede Brasileira pela Integração dos Povos—GTPI /Rebrip*). The working group[81], created in 2001 as a result of the WTO dispute between Brazil and the United States, now includes patent lawyers and trained pharmacists. The GTPI does not play a direct role in negotiations between the government and industry, but maintains pressure through formal organizations like the National Health Council and through informal channels of communication, mainly through the National AIDS Program. For example, Carlos Passerelli who had worked at Brazilian Interdisciplinary AIDS Association (*Associação Brasileira Interdisciplinar de AIDS*—ABIA*)* and headed the GTPI, now works as the international coordinator at the National AIDS Program.

The weakest link in the *triple alliance* is the relationship between AIDS NGOs and the domestic pharmaceutical industry. There have never been formal channels of communication and mutual support between the two groups. Activists do not want to be

[81] GTPI is comprised of the following local NGO groups ABIA, CONECTAS, GAPA – SP, GAPA – RS, Gestos, GIV – Grupo de Incentivo a Vida, INESC, INTERVOZES, and Pela Vida, as well as international groups MSF and OXFAM.

viewed as pawns of private sector interests.[82] Industry typically does not view activists as necessary allies to press for government policies. Nonetheless, during the 2005 Kaletra negotiations, NGOs sponsored studies detailing the capacities of Brazilian industry, and representatives of the pharmochemical sector gave presentations to local activists concerning local industry's capacity to produce patented ARVs. Several interviewees from industry specifically mentioned the actions of Pedro Chequer, NAP's director during the Kaletra negotiations, in reaching out to the country's pharmochemical sector.

The *Triple Alliance* in Action: Efavirenz and Tenofovir

Each confrontation between Brazil's government and transnational pharmaceutical companies has strengthened the triple alliance between activist bureaucrats, civil society, and local industry. During the first threats of a compulsory license and the WTO dispute in 2000-2001, Paulo Teixeira, Brazil's AIDS director at the time, recalled how the National AIDS Program reached out to NGOs for support. Missing from this alliance, however, was the participation of domestic private-sector drug companies. This latter group became incorporated during the first term of Lula's government starting in 2003 with the announcement of industrial policies. State support for the pharmaceutical sector gained salience with the new administration, especially during the 2005 negotiations for Abbott's Kaletra. From 2006 onward, the roles of the triple alliance have become more defined. The cases the ARVs efavirenz and tenofovir illustrate this point.

[82] In fact, many interviewees related cases in which a drug company sponsors a patient group to sue the government so that the state would purchase their medicines.

Brazilian health officials began to mobilize for a compulsory for efavirenz in January of 2007 after it appeared that Merck would not budge in its negotiating position. Between the start of the year and May 2007 when efavirenz was declared in the public interest, the National AIDS Program began to articulate with its NGO base. Passerelli (2007) explains the interlocution:

> In the case of efavirenz in my area, we made consultations with certain organizations to see if we would have the support of civil society in the case of a compulsory. We knew we could count on their support, but other sectors of the government didn't know what type of political support could be obtained. So we did these meetings and concluded that Brazilian civil society supports the measure. We started with ABIA as the representative of REBRIP. We also talked with MSF.

But NGO groups remained cautious in their support. Protests, mobilizations, and even lawsuits failed to force the government to issue a CL for Kaletra in 2005. Gabriela Chaves (2008), a pharmacist who works at ABIA and the GTPI explains the situation and the role carried out by her organization:

> Within the movement there was discussion on how to support it. We had to support the measure but not completely. We were already disappointed in the case of Kaletra. But we were there when Lula signed it, and it was extremely emotional, and then the pressure from the media and industry began. Industry ended up attacking the measure with all sorts of arguments. ABIA mapped out and responded to all the arguments that industry did in the media against the CL…We said this is an important step for the country. In that way, we supported the government's measure and did them a favor. We did that pamphlet in two weeks. We tried to get a space in the public opinion and we achieved it…

NGOs thus played an important role not only lobbying for the use of TRIPS flexibilities and voicing their political support, but also, and perhaps more importantly, explaining the implications of the measure to patients. In the face of allegations concerning the quality of generic drugs, legal issues related to employing the use of CLs, and threats to continued supplies and future innovation, the assurances by activists helped to allay public doubt and concern.

The role of local industry was to assist in the local production of the drug. During the negotiations, Health Minister Alvares (2008) said that he received verbal confirmation from Eduardo Costa, FarManginhos' (FM) director, and from Costa's boss, Paulo Buss, the director of the FioCruz Foundation, that the Health Ministry's lab could have efavirenz ready in one year. (They ended up erring in their timeframe.) An agreement between the Ministry of Health and the federal lab was only signed after the CL was decreed. Pernambuco's public lab Lafepe was also selected to develop efavirenz since it had already developed a 200mg formulation of the drug, and its experience could be leveraged in developing the 600mg dose currently in use. FM, under the new modality of sub-contracting out production of the API, selected three Brazilian pharmochemical companies to produce the raw material—Cristalia, Nortec, and Globe.

Scaling up production of efavirenz for 80,000 AIDS patients using the medicine remains a challenge for local labs and has tested their relationships with AIDS activists. The first batch of production was only delivered on February 2009—*21 months after the CL!* FM had even established a consultative council in January 2008 to incorporate the voices of civil society representatives. Activists, however, publicly decried the lab's lack of transparency and delays in launching new ARVs. Eduardo Costa (2008) responded by saying that FM had attempted two years ago to import the API prior to the CL, but faced legal injunctions by the patent owner. "If we consider that pilot batches only could be

carried out after the production of the API, we can see that the task was almost impossible," he defended.

Production of efavirenz also encountered technical problems when FMs' formulation failed bioavailability tests in May 2008. Costa admitted the public lab's error by not demanding Merck to provide all the technical details of its reference drug—as determined by the compulsory license decree—so that the generic copy would be identical (Cimieri 2008).

The struggles over tenofovir, a nucleotide analogue reverse transcriptase inhibitor marketed by US-based Gilead Sciences, also highlight the actions of the *triple alliance*. By 2007, there were close to 31,000 patients using the ARV. Per capita annual cost in that year stood at R$ 3,121, equal to R$ 89.8 million in expenditures. Brazil's negotiators were able to obtain a deep discount for 2007 purchases after the CL with Merck, but costs for the patented medicine remained high.

Local NGO analysts, working with public labs and international partners, noticed that the ARV was protected by a weak patent. In 2005, Wanise Barreto, a patent lawyer at Farmanguinhos, filed a pre-grant opposition to the patent of tenofovir with Brazil's national patent office (*Instituto Nacional da Propriedade Intellectual*—INPI). She argued that the drug company's request lacked novelty and inventive activity. GTPI obtained Barreto's pre-grant opposition and, combining its information with reviews by Indian partners, undertook a supplementary review of Gilead's patent request for the drug. It sent its review to the National AIDS Program and to the INPI. The patent office continued to delay a ruling on the Gilead's patent application, although it had been deposited in 1998. Chaves (2008) explained the next step:

> So the solution that we told the AIDS Program is to declare tenofovir in the 'public interest' for patent analysis so that we could accelerate the process to either produce it or purchase it internationally. We do not know what they are going to do. But we have done our part in providing them with information of what needs to be done… I am not always accompanying the negotiations, but am saying that it is expensive and that there is no reason why we should be purchasing it from Gilead. This is the worst case, knowing that you have alternative suppliers in China. There is no reason for it…

Brazil's Minister of Health ended up declaring tenofovir in the public interest; not as the first step in breaking the drug's patent, but to force the INPI to rule on the drug's patentability. Brazil's patent office ended up denying Gilead's patent in 2009, thus opening up the possibility for alternative suppliers and local production.

The only producer registered to sell the drug in Brazil is Gilead, but there are WHO-prequalified generic producers of the ARV in India. Consequently, Brazil-based ABIA teamed up with Indian NGO Sahara Centre for Residential Care & Rehabilitation to file a pre-grant opposition to Gilead's patent of tenofovir in India, too. For local production, the Ministry of Health chose Farmanguinhos and Minas Gerais state public lab Funed to develop and produce tenofovir in partnership with national API makers Globe, Nortec and Blanver (Ministry of Health 2009).

THE FATE OF BRAZIL'S TRIPLE ALLIANCE AND CORPORATE POWER

The State

The post-TRIPS era, with both China and India facing significant barriers in producing generic medicines, poses challenges and opportunities. In the future, health

officials may not have readily available alternatives when they contemplate using a compulsory license. The situation may create another opportunity for Brazil's public labs. Whereas many private pharmaceutical firms in developing countries may be restricted from developing generic versions of patented medicines due to strategic alliances or licensing agreements with originator companies, Brazil's public labs remain under the control of public health authorities. The two key obstacles faced by domestic policy makers are successful public-private partnerships and foresight when using the Bolar Exception, i.e. the legal provision that permits the lawful development of a patented drug but not commercialization until the patent expires.

Employing public labs to regulate prices of strategic medicines, ensuring the sustainability of the country's treatment program, and stimulating technological development requires state management that combines bureaucratic agility with market perspicacity. State managers must have foresight into the new medicines on the horizon that will become the future standards for treatment and mobilize resources for their early production. The process entails several risks that even public labs avoid. Since the reverse-engineering process can take one to three years to complete, funds must be made available for research partners to develop promising new drugs on the horizon. The risks can be socialized under the rubric of education and technological development, but the savings can be significant when negotiating prices with a patent holder of a high-priced strategic medicine.[83]

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[83] Brazil has also lagged behind in developing and offering more fixed-dose combinations of ARVs. Atripla, a one-a-day capsule combining efavirenz-emtricitabine-tenofovir, has become standard treatment in other countries. One reason why Brazil has lagged behind is that fixed dose combinations were banned in the 1980s after a number of products of dubious effectiveness appeared on the market. Only in 2004 did ANVISA come out with new regulations governing fixed-dose combinations. Pedro Rolim (2008) said that he has received money from FINEP (a technology funding arm of the federal government) to revamp his lab at the Federal University of Pernambuco and developed new ARV combinations in association with public lab Lafepe.

Efforts continue by Brazil's public labs to create innovative medicines and take advantage of early working provisions in patent laws. Interviewees were reluctant to discuss their development drug portfolios but acknowledged some problems. When asked why Farmanguinhos did not take advantage of the Bolar Exception more often, Andre Daher (2008), a physician who works at the R&D division of the lab, responded: "Maybe due to the traumatic experience with Kaletra in which there was a furious response by industry." The experience relates to Abbott's efforts to stop the lab from obtaining patented raw material of lopinavir used in the Kaletra formulation. Additionally, the lab must balance a number of demands from the Ministry of Health, and concentrate resources in treatment areas forsaken by private industry, such as pediatric formulations of ARVs and strategic objectives including drugs used to combat flu pandemics.[84]

The state is likely to continue building South-South coalitions to negotiate collective drug purchasing agreements and overcome technological obstacles. Brazil's National AIDS Program has spearheaded the International Network in Technological Cooperation in HIV/AIDS. The network, which includes China, Ukraine, Brazil, Argentina, Thailand, and Cuba, is focusing research efforts on developing technology used for soft-gel capsules of ritonavir as well as quality control of diagnostic kits.[85] The Ministry of Health also donates ARVs and technical support to other AIDS programs in South America and Portuguese Africa. In one instance, Brazil is donating pharmaceutical technology from FM so that Mozambique can establish its own ARV factory.

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[84] "The objective the public lab is not to have profit but to have a large therapeutic arsenal and offerings for special populations, i.e. treatment failure and pediatrics," explained Daher (2008).

[85] To become a member, countries must have three criteria: 1) committed to fight HIV/AIDS, 2) have a flexible approach to intellectual property; and 3) have technical capacity and scientific capability in the pharmochemical and/or pharmaceutical sectors.

Civil Society

The most enduring legacy of Brazil's experience with contentious AIDS policies is the strong coalition between activist groups outside of government and social movement insiders, especially in the National AIDS Program. Until there is a cure for AIDS, this coalition will continue to reinvest the "reputational dividends" of Brazil's banner program.

The success of this AIDS coalition rests on the ability to ensure alternative suppliers of essential medicines. The 2005 dispute over the price of Abbott's Kaletra is a case in point. Advocacy groups mobilized protests, lobbied the National Council of Health, and filed lawsuits to force the government to issue compulsory licenses. Despite their efforts, policy makers backed down. One of the overriding concerns was the availability of generic copies. Local Brazilian producers would take six months to three years to make the first batches available, and equivalent medicines from Asia still had to go through the necessary safety tests. Regulatory approval could have been fast-tracked, but authorities would still be vulnerable to accusations of sub-standard quality.

Activists continue to provide support to public labs and are also reaching out the local industry. The link between activists and national bourgeoisie is likely to remain the weakest link in the triple alliance but also the area with the most potential. The implementation of industrial polices provides an opportunity for social accountability of state support for the local production strategic medicines.

Lastly, Brazilian organizations are likely to continue establishing more South-South links with activists in other countries. Connections with Indian activists have already begun due to the importance this Asian country plays in providing medicines, but

alliances and mutual support will also likely to grow with groups in other countries facing patent monopolies.

National Bourgeoisie

Brazilian firms (whether public labs or private sector firms) are being squeezed by both patent monopolies from above and market pressures from below. Besides patent restrictions on the lawful copying of medicines, they face increasing competition from generic suppliers in Asia. To confront patent power and market power, Brazil's pharmaceutical sector has received support from the government's new industrial policies.

State support, however, has not been sufficient for the two companies that first began producing active principals—Labogen and Microbiologica. The former went into bankruptcy after Rio de Janeiro public lab Instituto Vital Brazil (IVB) failed to pay its debts to Labogen for raw materials supplied to make ARVs and also due to its inability to compete in international tenders, explained Marcelo Neto (2008), Labogen's former director.[86]

Microbiologica continues to work in some areas related to AIDS, but now survives as a contract research company producing small batches of ARVs under development by transnational drug companies and exporting high-end products used as references for biological testing in the US. Lelio Maçaira, who left Microbiologica, now

[86] Neto (2008) also stated: "If the government does not set a market guarantee of some say 40% of purchases, I think the API manufacturing sector will continue to disappear. Nowadays, no one wants to work on AIDS medicines. It is a waste of time. Only now the government began to do some changes to the Tender Law and some industrial policies. But the private sector does not have time to wait, the government does."

operates a contract manufacturing company, Laborvida, producing medicines for both originator and generic medicines. His firm even won a bid to manage IVB's outsourced production.

Global integration in the private sector, meanwhile, continues apace. In April 2009, French company Sanofi-Aventis purchased Brazil's third largest generic drug maker Medley for R$ 1.5 billion (about $750 million). Historically, expansion of Brazil's privately owned drug companies have resulted in increased foreign penetration in the form of mergers and acquisitions by TNCs. This route to financial success chosen by Medley's shareholders represents a challenge to policy makers at the BNDES who are contemplating sector policies to forge a domestic, privately owned mega-pharmaceutical company, capable of competing head-to-head on the global market (Agência Estado 2007). In the near future, the national drug companies will be able to count on the support of the Brazilian state for industrial and technological development.

Transnational Drug Companies

At this current conjecture, foreign capital is unlikely to become a member of Brazil's development alliance as it once was before neoliberal reforms of the 1990s. The uniformity of intellectual property laws across the world has increased their structural power. Given current trends, however, they are unlikely to obtain bilateral support from the US in specific IP disputes. Rather, US diplomats will focus their attention on bilateral trade agreements and international treaties to ratchet up intellectual property standards.

In light of Brazilian attempts to become more self-sufficient in medicines and economize fiscal resources spent on ballooning health budgets, what strategies and tactics

have worked best for foreign-based firms to pursue patent power and avoid compulsory licenses? Of course, they could always acquiesce to commodity prices demanded by the Brazilian government. Apart from this unlikely outcome, the Brazilian case demonstrates the success of some corporate approaches versus others.

Bristol-Myers Squibb (BMS), for example, has had fewer problems with government negotiators compared to other firms. Unlike Merck Sharpe and Dohme (MSD), which lost about $30 million when the compulsory license for efavirenz was issued in 2007, BMS has never had market exclusivity of one of its ARVs threatened by the government. Most drug companies use some form of tiered pricing set by global headquarters and based on a country's GDP per capita and HIV/AIDS prevalence rate. Local officials at BMS took a different approach and convinced the corporate head office to provide them with increased autonomy to establish the price of ARVs closer to that of least developed countries. When the National AIDS Program began to distribute atazanavir in 2004, BMS deviated from its global price guidelines and gave Brazil a deeper discount. Salles (2008), the head of corporate relations, explained that one of the reasons was to avoid conflicts over prices.[87] BMS' strategy is to project its image as a partner instead of being viewed as an obstacle in Brazil's success.

Another strategy employed by BMS is to stay ahead in the technological curve, even at the level of formulations. After Brazilians began to produce didanosine, BMS introduced an enteric-coated formulation that includes an extended release mechanism so that only one tablet, as opposed to two, is taken each day. The National AIDS Program began distribution of the advanced formula in 2002, and while Farmanguinhos said it is

[87] Market success can breed its own problems. As BMS's atazanavir wins more market share from Abbott's Kaletra, the company's sales being to claim a larger percentage of the government's budget for ARVs. Civil society groups have begun to lobby health officials to threaten its patent.

developing a version, to date no local generic has been approved by the regulatory authority ANVISA.

CHAPTER SUMMARY

This chapter argued that industrial policies increased state autonomy by securing the support of the local bourgeoisie. These state policies marginalized the interests of transnational drug companies and gave preference to the local pharmochemical sector. AIDS has been at the forefront of industrial policies for the pharmaceutical sector, but as state elites return to the business of economic development, policy-making concerning the disease has been subsumed under the goal of economic development. Not even the compulsory license of efavirenz, marketed by Merck, in May 2007, generated significant social protest since new domestic agendas and alliances had been firmly established.

This chapter recounted the institutionalization of the *triple alliance* between the government, local pharmaceutical sector, and patient advocacy groups. At the center of the alliance is the Ministry of Health: with local industry, public-private partnerships were established using public labs to produce strategic medicines; and with local NGOs, information and political support are exchanged concerning the impact of breaking patents on its treatment program. The weakest link in the triple alliance is between AIDS activists and local industry. Nevertheless, there is growing awareness of the challenges and obstacles of obtaining technological autonomy in the global division of labor in pharmaceuticals.

CHAPTER SIX – SUMMARY AND CONCLUSIONS

Most of Brazil's population are absent from
this analysis because they are absent from
the decision making that is being described…

--Peter Evans, *Dependent Development* (1979: 13)

Brazil has rediscovered itself, and this rediscovery is being expressed in its people's enthusiasm and their desire to mobilize to face the huge problems that lie ahead of us.

--Luiz Inacio 'Lula' da Silva, President of Brazil

SUMMARY

This dissertation has argued that a national triple alliance developed in order to defend a domestic social program in the face of globalizing pressures and norms by analyzing the case of Brazil's response to the AIDS crisis. I have also argued that the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) has increased the structural power of transnational drug corporations in their relations to the developing country states. Lastly, I show the triple alliance contests the structural power of corporations by exploiting the "reputational dividends" of its successful AIDS social program.

Brazil's implementation of neoliberal economic policies during the early 1990s strengthened the power of transnational drug companies (TNCs) to obtain monopoly

rents. The passage of new intellectual property legislation in 1996 allowed firms to use Brazil's justice system to enforce their patent power. Market de-regulation, trade liberalization, new property protections also produced countervailing social forces. By the end of the decade, the state began to re-assert its control over pharmaceutical markets. And, more importantly, it began to do so without the help or guidance of TNCs. The former triple alliance between state, TNCs, and local capital, alluded to in Evans' quote above, had disintegrated.

In the democratic spaces that opened up in Brazil during the 1990s, some mobilized groups were able to make rights claim on the state more than others. Brazil's public health system was in shambles and access to basic medicines under threat. The one exception was Brazil's AIDS program, which resulted from a strong coalition between activist AIDS NGOs (mainly urban, middle-class citizens affected by the disease and the high price of drugs) and activist health reformers that transformed the "right to health" into a concrete social program.

Leadership at the highest levels of government, such as astute politicians, played an important role in opening up spaces to allow for successful AIDS policies, in part because of the political gains to be made. But more important were the mid-level bureaucrats who circulated in and out of the revolving door between public administration and advocacy groups. These actors represent the "social movement insiders" (Santoro and McGuire 1997) that forge alliances with activists outside of government and lobby for policy from within. This constellation of forces were able to pass a law making it the obligation of the state to provide free and universal access to AIDS medicines to all those in need.

During the 1990s, the dual coalition had focused their attention on national issues concerning access to medicines and sufficient fiscal resources. The situation changed

when the sustainability of the program came under threat from the high prices of patented medicines. Ever since the US threatened a WTO panel in 2000 against Brazil, the National AIDS Program has mobilized its local NGO base and reached out to international human rights groups to defend its cause. Brazilian diplomats, known for a strong tradition of professionalism and excellence, increased collaborations with AIDS bureaucrats and skillfully constructed alliances with other countries to push a health rights agenda in international venues. In sum, they exploited the "reputational dividends" of Brazil's successful AIDS program to contest US hegemony and corporate power.

Building alliances with the local bourgeoisie occurred after the weaknesses of Brazil's pharmaceutical capacities became apparent. The evolution of the local production of ARVs has evolved through a number of institutional settings over the past two decades. At the start of the 1990s, Microbiologica reverse engineered the AZT molecule to become the first Brazilian maker of the medicine. Its experience was not nurtured when Farmanguinhos, operated by the Ministry of Health, was mobilized to quickly produce generic copies of ARVs not protected by patent.

When the government scaled up production and called on the nation's scientists to respond to the AIDS crisis, informal collaboration across the public-private divide developed and the country's best minds made contributions. But the joint efforts were fleeting. Brazil failed to keep pace with technological trends due to changes in the organization of public labs and impact of patents on second generation ARVs. Only after the contentious politics of breaking patents and paucity of off-the-shelf alternatives exposed the weakness of Brazil's pharmochemical base did Brazilian policy makers ramp up support for local private API fabricators and formalize partnerships between public and private drug companies.

The unforeseen consequence of US pressures, panels at the World Trade Organization (WTO), and price disputes was the resurrection of parts of Brazil's *dirigiste* policies of the past to direct the development and import substitution of inputs for its growing health system. The election of Luiz Inácio Lula da Silva provided the backdrop to industrial policies designed to support the country's national bourgeoisie. The key private sector actor has been ABIFINA, the industry association representing the pharmochemical sector. State directed industrial policies have translated into technical, legal, and political support from this industrial segment when the state has had to confront external forces.

Communication within the "triple alliance" and instrumental use of "reputational dividends" rests upon a frame of human rights. The right to health care, enshrined in UN conventions, provides a common discursive framework for institutional insiders, domestic activists, and NGOs with a global media presence. Specific frames have shifted during each conflict over patents and high prices. For example, when Brazil finally issued a compulsory license, debate increased over the impact on the country's economic development.

The frames employed by transnational drug companies and their backers were less coherent and more variable. Initially, they purported the breaking of patents as tantamount to theft. Later attempts by pharmaceutical companies to frame themselves as the reason behind the success of the program since they invent the medicines (thus justifying patents and high prices) also floundered. In the end, they were forced to concede to government demands for price discounts and wanted to be seen as partners in the Brazil's flagship AIDS program.

The particularities of AIDS cannot be over-emphasized for understanding Brazil's success. The stigma attached to the "gay cancer" mobilized a group that achieved strong

internal group solidarity due to their identity within and across countries. Brazil's gay community combined identity politics with rights-based claims. Their middle- and upper-class origins, urban location, and foreign networks made them both vital stakeholders in the programs' success as well as key promoters.

As the sustainability of the program became intertwined with the technicalities of intellectual property law and pharmaceutical production, social movement organizations adapted. Hiring more professionals and developing denser networks to other Southern countries permitted them to share technical information with partners both inside and outside of government.

THEORETICAL IMPLICATIONS

The case of Brazil provides a number of useful theoretical insights. My first theoretical point is that globalization has resulted in a triple alliance consisting of the state, local bourgeoisie, and domestic grassroots organizations tied into transnational advocacy groups. This coalition is contrary to what theories of globalization and the state predict. Global capitalist theory envisions the increasing coherence of a "transnational capitalist class" based on a common interest in global accumulation (Sklair 2001; Robinson 2004). Centralization of power in such institutions like the WTO, however, has reinvigorated national coalitions in defense of national projects and sovereignty.

The triple alliance is the consequence of neoliberal reforms and global capitalist institutions. Neoliberal reforms in developing countries may represent an agenda of global accumulation, but a minimalist state also precludes strong alliances between the state and TNCs embodied in previous conceptions of development alliances (Evans

1979). With trade liberalization and intellectual property protection, global tech firms no longer have to negotiate with states to gain access to markets in exchange for transferring technology and investing capital.

States, however, remain interested in ascending technological ladders and creating high income jobs. The local bourgeoisie in developing countries still requires state support to promote local skills, rebalance national markets, and assist in global insertion. In Brazil's experience supporting a domestic AIDS program, the unforeseen consequence of a formalized institution like the TRIPS accord is the weakening of the transnational alliance and strengthening of domestic coalitions. Evans' (1979) triple alliance pushing for industrialization consisting of state managers, TNCs, and domestic bourgeoisie has shifted—TNCs have exited as social movements have entered.

The second theoretical point is that TRIPS has increased dependency in the Third World by strengthening the structural power of capital. Patent monopolies have undoubtedly increased the bargaining power of TNCs. On balance, foreign drug firms have profited handsomely from Brazil's universal AIDS program. Between 1996 and 2007, the Brazilian government spent a total of $2.71 billion on ARVs. Of this amount, foreign firms received $1.85 billion[88] or 68% of the total. "I wish every disease could have a Henfil or Betinho," stated Antonio Salles (2008), the Director of Corporate Relations at Bristol Meyers Squibb, referring to two famous Brazilians whose death from AIDS helped generate support for public policies.

Brazil's experience with patent power codified by TRIPS follow the predictions of many theories about globalization. In the past, developing countries moved into advanced industries by copying technologies from the first world. As a result of the

[88] In 2005 US dollars, based on data from Brazil's National AIDS Program.

Industrial Property Act of 1996, Brazilian firms no longer could quickly reverse engineer and market next generation ARVs. In this sense, global capitalist institutions constrain state actions (Wade 2003; Chang 2002).

Even using the flexibilities outlined in TRIPS represents a structural advantage for TNCs. The process of developing patented medicines and using compulsory licenses has been embroiled in court injunctions, WTO panels, and threats from drug firms and US diplomats. With new intellectual property legislation, policy makers must engage in difficult price negotiations and follow a bureaucratic and politicized process when issuing a compulsory license. The power of TRIPS is ultimately expressed by the fact that Brazil never became an export platform in AIDS medicines.

The structural power of capital, however, does not necessarily lead to the end of state autonomy as theories of globalization depict. If we understand the state as occupying a unique institutional "arena" in modern society (Mann 1986), then globalization opens new spaces at the same time as it restricts others. The "arena" grows as new actors' voice legitimate claims, and state autonomy is renewed by the ability of state elites to play different societal forces against one another.

Democratic reforms that have occurred in the Third World over the past twenty years represent the entrance of new actors with demands on states. The ensuing political struggles resulted in the creation of new state agencies responsible for managing social programs. Here, state construction is not as deterministic as the structuralist perspective of capitalist states leads us to believe, but instead can result from the scaling up of rights-based social struggles and programs.

The forging of state autonomy in the age of globalization goes beyond the mere balancing of forces, be they driven by rights-based claims and/or the interests of TNCs. A view of autonomy resulting from the mediation of different political and economic

interests alone reduces our conception of the state to acting within territorial boundaries. This traditional view of the state views power projection that extends beyond national boundaries solely in geopolitical and military terms.

Globalization, however, allows us to also include the symbolic elements of state autonomy in novel ways. This leads to my second theoretical point: states can increase their autonomy in the world system through successful exploitation of rights-based social policies and programs, or what I call "reputational dividends." This may occur when a state addresses any social issue, but is particularly acute with respect to AIDS. Where the disease is left unchecked, it devastates governments both materially in terms of personnel but also symbolically for failure to act. Those countries that successfully confront the pandemic become empowered. Seen as "winners" in the fight against the pandemic, policy experts, activists, and even private companies rally to the cause. Consequently, as AIDS became more of an international concern and the success of Brazil became more apparent, Brazilian health officials positioned the country as a leader in the fight against the disease and victim to the interests of the transnational pharmaceutical industry.

Social theory speaks of the "reputational costs" that weak actors can impose on strong actors (Greenhill and Busby 2008). But equally important are the symbolic gains actors can obtain. Whereas "costs" can be imposed on the misdeeds, hypocrisy, and violations (i.e. negative behavior) of states, "dividends" can be reaped by exploiting achievements, moral appeal, and good deeds (i.e. positive behavior). In international relations, those countries best posed to take advantage of the latter are middle income countries. Low-income countries tend to have scarce resources either to carry out a successful program comparable to that of Brazil or the required skills to trump up their

case on the international scene. Rich countries, in the case of attacking intellectual property rights, tend to have most to lose in these zero-sum game situations.[89]

Globalization theory predicts that to contest global capital, social movements would have to internationalize. The Brazil case demonstrates this point. Rights-based claims became a mobilizing factor for networking with various groups from gay activists, the access to medicines movement, and human rights defenders across the world. Equally important is that activists had a concrete program to defend, not an abstract ideal. Politicized coalitions can scale-up success from the local to the national and to the global levels. Social movements could not have achieved this success without state partners, and state actors could not have contested global power without outside help.

Brazil's success in AIDS has strong implications at the international level. Kapstein and Busby (2010) draw important lessons from the construction of the first global entitlement scheme, which transformed ARVs from private goods to merit goods available to everyone. These lessons include permissive material conditions in the form of an inexpensive good or service, policy consensus about what needs to be done, and a broad political coalition built on adroit framing of the issue.

My Brazil-centric perspective adds that middle-income countries need to be at the center of this process. Their limited resources but sufficient institutional capacity to universalize a good or service, combined with their position in the world system to craft moral claims, make them ideal candidates to develop "reputational dividends." Transnational advocacy networks when partnered with these states are able to distribute these "dividends" to other developing countries.

[89] This middle-income thesis is analogous to Eric Wolf's (1999) middle peasant thesis.

FUTURE DIRECTIONS FOR RESEARCH

Comparing Brazil's case to the experiences of Thailand, South Africa, and India could refine the theoretical conclusions of this dissertation. All these countries suffer from a severe AIDS epidemic, host locally owned pharmaceutical companies, and have incorporated TRIPS into local legislation, as a result of being under constant pressure from the US. These countries' integration into the global economic system places greater demands on them in terms of competitive development in the knowledge-based economy and upholding human rights obligations.

Despite their commonalities, the four countries vary in terms of their approach to addressing the AIDS epidemic and commitment to providing universal public health. India and South Africa have denied (until recently) the seriousness of the disease within their countries. Both have an under-resourced public health system, but are home to strong generic drug companies. Indian firms, in particular, have spearheaded efforts to reduce the price of AIDS medicines and have become major suppliers to other countries suffering from the pandemic.

Compared to India and South Africa, Brazilian and Thai public health authorities have overcome the stigma attached to the disease and enacted aggressive policies in partnership with civil society groups. These countries also are home to public (state-owned) drug companies that produce AIDS medicines for their national treatment programs. These public labs not only promote the use of TRIPS humanitarian safeguards, but also engage in South-South networks to develop and disseminate public pharmaceutical technologies. South-South activist networks between Brazilian and Indian NGOs have also expanded.

These additional cross case comparisons should provide a number of insights for theory generation about social responses to the AIDS pandemic, globalization, and state autonomy. First, how do successful AIDS programs lead to state empowerment when developing countries confront transnational drug companies? How does the internal organization and embeddedness of these states affect coalition building? Does stigma attached to the disease and homosexuality affect coalition building between activists in the access to medicines movement, gay rights organizations, and industry associations representing domestic private firms?

Another set of questions concerns the relationship between global capital and states and the chances of replicating the successes of rights-based social programs and policies. How do relations between states and TNCs on the international level affect relationships between states and social movements on the domestic scene? Why do some social programs become rallying points for social mobilization and others do not? And lastly, why do some domestic social struggles become scaled up to the global level while others are not?

The AIDS crisis tests the ability for societies to respond to catastrophic challenges and uphold human rights obligations. Globalization presents new demands on developing countries, but also new opportunities. Comparing Brazil's experience in producing medicines locally in the brave new world of patents with those of other countries responding to the AIDS crisis, nonetheless, could provide insight into how different governments relate to social pressures coming from both civil society and industry. The analytic framework focusing on the interaction of committed bureaucracies and the globalizing dynamics of contention could help explain varied outcomes dealing with a variety of crises in the developing world, be they related to the economy, environment, or health.

APPENDIX ONE: CHRONOLOGY OF POLICIES AND EVENTS CONCERNING BRAZIL'S PRODUCTION OF ARVS, PATENTS AND PHARMACEUTICAL INDUSTRY

Date	President	Minister of Health	FarManguinhos Director	ARV Production	Policies related to Patents	Policies related to Public Labs and Industrial Policies
1971					Dec- Industrial Property Act (CPI N.° 5.772): removes patents on pharmaceutical processes and products	Central Medicines Agency (CEME) created.
1983						First AIDS case diagnosed in Sao Paulo
1985	*Military Rule Ends. Start of Democratic Transition*					National Program in STD-AIDS established
1988	Jose Sarney				*New **Constitution** approved that enshrines health as a right for everyone and state's duty to insure universal and equal access to health care.*	
1989						Sao Paulo state begins to distribute AZT treatments
1990	Fernando Collor					**SUS** (Unified Public Health System) institutionalized (Laws 8.080/90 and 8.142/90)
Early 1990s						Pharmaceutical imports liberalized and prices deregulated
1992	Itamar Franco	Adib Domingos Jatene		**Microbiologica (MB) launches 'Brazilian AZT'**		**Public Procurement Law** (Law 8.666) approved
1993				Labogen produces first batch of AZT APIs		
1994			Eloan Pinheiro	Lafepe begins to produce AZT MB launches d4T	Dec.-Decree 1.355 internalizes TRIPS accord	
1995	Fernando				World Trade	

	Henrique Cardoso				Organization created and Brazil a member	
1996		Carlos César Albuquerque		Lafepe produces AZT pediatric formulation	May- **Industrial Property Law** (#9.279) passed that includes pharmaceuticals, processes and products	Law passed insuring universal access to AIDS drugs (Sarney Law 9.113/96)
1997					Industrial Property Law implemented	CEME deactivated amidst allegations of corruptions and inefficiency. Far-Manguinhos mobilized by Ministry of Health to make copies of ARVs.
1998		Jose Serra		**Scale-up of ARV production** Labogen and MB launch D4T API	Dec.-Phrma requests USTR to list Brazil as a Watch List country on its annual "Special 301" Report and complains about Brazil's lack of IP protection.	
1999	*January-Monetary Devaluation*			Labogen launches DDI API	Decree # 3.201 establishes criteria for compulsory licensing for national emergency and public interest	Jan. National Health Surveillance Agency (**ANVISA**) (Law # 9.782/99) created to regulate pharmaceutical market.
					Dec.-ANVISA Prior Consent Established by Presidential Directive (Medida Provisorio 2.006/1999)	**Generics Act** (Act # 9.787/99) passed that stimulates production and use of generic medicines.
						Price controls put into place
2000				Nortec and Cristalia enter the ARV market Labogen launches NVP API	May-USTR ranks Brazil among the Watch List countries of its "Special 301" Report.	Congressional Investigation Commission (CPI) into Medicines
2001					Feb.-ANVISA Pre-	Law 10.332/01 CT-Saúde. Setorial

					Approval passed into Law	Fund for health technologies created
					Serra threatens CL for Merck's efavirenz and Roche's nelfinavir but reaches accord with both.	Nov.-Doha Declaration affirms the right to health over right to property at WTO
					Jan.-June: WTO Trade spat between US and Brazil over 'local working' clause concerning patents.	
2002		Barjas Negri (Jose Serra begins campaign)		Dec.- Brazil launches the International Cooperation Program, which would provide about 10 countries with needed ARVs.	Dec.-Law # 10.603 passed providing protection for undisclosed data provided by drug firms to ANVISA.	
2003	Luiz Inacio 'Lula' da Silva	Humberto Sergio Costa Lima	Nubia Boechat	Modernization Program of Public Drug Production launched to invest US$26 million in public labs	Decree # 4.830/03 allows parallel importing of patent products under a compulsory license from countries in which product not patented. May-USTR elevates Brazil to the Priority Watch List of its "Special 301" Report.	Medicines Regulation Body (Câmara de Regulação de Medicamentos) created to oversee price increases of medicines- Nov.-Guidelines drawn up for Industrial Policy for Technology and Foreign Trade (PITCE) and pharmaceuticals included.
2004				Labogen ends production of ARV raw materials and later closers its doors	May-USTR ranks Brazil among its "Special 301" Report's Priority Watch List countries.	Law 10.973 Incentives for Technological Innovation
2005		José Saraiva Felipe		NAP and FM sign accord to develop efavirenz, tenofovir,	Costa issues 'public interest' of Abbott's Kaletra. Saraiva Felipe	Industrial policy Profarma implemented by state-owned investment bank BNDES to stimulate

				Kaletra, atazanavir, and didanosine EC Ministerial Order nº 2438/05 - Network of Public Labs Created to coordinate production and investments	reaches an accord. US Congress members request USTR to impose economic sanctions on Brazil should it issue CLs.	domestic pharmaceutical production. Law 11.196 [Lei do Bem]
2006		Agenor Alvares	Eduardo Costa	FM authorized to export medicines and begins Service Production Contracts to local pharmo-chemical firms.		
2007	Lula begins second term	José Gomes Temporão		FM 'sub-contracts' production of efavirenz API to national labs Cristalia, Nortec and Globe	Apr.-Ministry of Health issues **first compulsory license** for Merck's efavirenz Apr.-USTR demotes Brazil to the Watch List on its annual "Special 301" Report; Phrma requests out-of-cycle review in lieu of the CL. May-Lula announces CL	
2008					Ministry of Health declares Gilead's tenofovir to be in the public interest in order to speed up INPI's patent evaluation of the product. INPI denies patent concession.	Ministerial Order nº 374/08 – Program to Stimulate Public Production in Health Industrial Complex Ministerial Order nº 375/08 – Program to Qualify and Certify private sector producers of inputs for health sector Ministerial Order n 978/08 – List of Strategic Medicines

APPENDIX TWO: LIST OF INTERVIEWS, INSTITUTIONAL VISITS AND CONFERENCES

Interviewee	Professional Title or Relevance to Research	Date(s) Interviewed
NGOs/ Patient Advocates		
Jorge Beloqui	Grupo de Incentivo À Vida	11 Jul 08
Gabriela Chaves	Pharmacist, ABIA/MSF Coordinator	27 Mar 08
Michel Lowtroska	Doctors without Borders, Representative of Access to Essential Medicines Campaign	25 Mar 08 and 30 Jun 05*
Renata Reis	ABIA Intellectual Property Coordinator	5 May 08
Mario Scheffer	Grupo Pella Vida/São Paulo	4 Apr 08
Rodrigo de Souza Pinheiro	Fórum de ONGs/Aids do Estado de São Paulo	2 Jun 09
Veriano Terto	ABIA, general coordinator	4 July 05*
OUTSIDE EXPERTS		
Octavio Antunes	Chemist, Federal University of Rio de Janeiro	29 May 08
Hayne Felipe	Far-Manguinhos/Popular Pharmacy Program	17 Jun 05* and
James Fitzgerald	Pan-American Health Organization	20 Oct 08
Lia Hasenclever	Economist, Federal University of Rio de Janeiro	16 Jul 08
Luis Felipe M Lima	Former ANVISA Director	12 Jul 05* and 28 Nov 07
Rosali Tardelia	Editor, Agencia Aids News Service	8 Jul 08
PUBLIC LABS		
Nubia Boechat	Former Director, Far-Manguinhos (2002-2005)	Jul 05* and 29 Mar 08
Josiana Gomes Chaves	FUNED, Assistant to the President	30 Jul 05*
Eduardo Costa	Director, Far-Manguinhos (2006-2009)	15 June 09
Jorge Costa	Vice President of Research, Far-Manguinhos (2006-present)	Questions Emailed / Never returned
Andre Daher	Manager, Clinical Testing, Far-Manguinhos (2002-present)	17 Jul 08
Carlos Alberto Pereira Gomes	Ministry of Health (1998-2001), Director of Funed, ALFOB	25 Aug 08
Ricardo Oliva	Director FURP, and President of Public Labs Industry Association (ALFOB)	17 Dec 08
Eloan Pinheiro	Director Far-Manguinhos (1994-2001)	25 May 06*
Cida Rodrigues and Gleide Gloria Silva	Head of Production and Assistant to the President, Iquego	14 Dec 07
Tuyoshi Ninomya	FURP, Technical Assistant	17 Jul 05*
Leduar Guedes	Superintendente Director, Lafepe	23 Jul 08
Pedro Rolim	Former director of production and R&D, Lafepe	24 Jul 08
PRIVATE NATIONAL INDUSTRY		
Vera Valente	Director, Pro-Genericos	18 Aug 05
Edson Lima	Director, API Manufacturing Division, Cristalia	6 May 08
Lelio Maçaira	Former Director Microbiologica, Director Laborvida	28 Nov 07 and 19 May 09
Otavio Pacheco	President, Cristalia	8 Jul 08
Jaime Rabi	Director, Microbiologica	16 Mar 08
Marcos Soalheiro	Director of Development, Nortec	17 Jun 08
Marcelo de Machado	Former Director, Labogen	7 Jul 08

Campos Neto		
Ciro Mortella	President, Brazilian Pharmaceutical Industry Federation (Febrafarma)	3 Sep 08
Nelson Brasil	Vice President, Brazilian Association of the Fine Chemical Industry (Abifina)	30 Jun 08
BRAZILIAN CIVIL SERVANTS		
Agenor Alvares	ANVISA Director, present; Minister of Health, 2006-2007	12 July 08
Dirceu Barbano	Head of Department of Pharmaceutical Assistance under Temporao	Questions Sent / No reply
Jarbas Barbosa	Director, Health Surveillance, Ministry of Health under Costa; PAHO	23 Oct 08
Paulo Buss	President, FioCruz (2001-present)	Too Busy
Pedro Chequer	Director, National AIDS Program, 1996-2000, 2004-2006	12 Jul 08
Fernando Cardenas	Ministry of Health, 1999-2002; NAP, 2002-2003	10 Jul 08
Norberto Rech	Director, Pharmaceutical Assistance, under Costa	10 Sep 08
Humberto Costa	Minister of Health, 2002-2005	22 Jul 08
Saraiva Felipe	Minister of Health, 2005-2006	12 Dec 07
Platão Fischer	Head of Department of Pharmaceutical Assistance under Jose Serra	Denied
Moises Goldbaum	Secretary for Science, Technology, and Strategic Resources, Ministry of Health (2003-2006)	Questions Sent
Alexander Grangeiro	Director, National AIDS Program 2003-2004	7 May 08
Reinaldo Guimaraes	Secretary of Science, Technology and Strategic Inputs, Ministry of Health, 2007-present	Too Busy
Liane Lage	Director, Drug Patent Review Office, National Intellectual Property Institute	15 Jul 08
Luiz Carlos Wanderley Lima	ANVISA, Intellectual Property Coordination (COOPI)	27 May 08
Barjas Negri	Minister of Health, 2002; Executive Secretary, 1998-2001	Denied
Pedro Palmeiro and Luciana Xavier de Lemos Capanema	BNDES, Manager and Engineer of Chemicals for Health Division	14 Aug 05*
Carlos Passarelli	International Programs Coordinator, National AIDS Program	13 Dec 07
Andre Luiz de Abreu Porto	General Coordination for the Development of Pharmaceutical Production and Inputs, Ministry of Health	7 Aug 08
Rubens Ricupero	Brazilian Diplomat to GATT Negotiations and former President of UNCTAD	15 Oct 07
Paulo Teixeira	Director, National AIDS Program, 2000-2003	7 May 08
Ana Paula Telles	General Coordination of Logistic Resources, Ministry of Health	11 Dec 07
Marco Antonio Vitoria	Physician, National AIDS Program, World Health Organization	15 Aug 06*
TRANSNATIONAL DRUG INDUSTRY		
João Domenech	Commications Director, Glaxo Smith Kline	Denied

Jorge Raimundo	Former Director, Glaxo Smith Kline, Currently at Interfarma	20 Jun 08
Irapuan de Oliveira	Director, Institutional Relations, Abbott	Denied
Antonio Salles	Director of Government Corporate Relations, Bristol Myers Squibb	8 May 08
Paul Singer	Vice President, Pharmaceutical Research Manufactures of America (PhRMA)	5 Aug 07*
Joao Sanches	Merck Dohme & Sharp (MSD), Communications Director	1 Mar 08
Joe Steel	Vice President, Commercial Development, Gilead	Unsuccessful/Questions Emailed
Joao Carlos Ferreira	Director, director of Institutional Relations and Legal Affairs, Roche	11 Jul 08
Felix Figols	Director, Institutional Relations, Boehringer Ingelheim	Denied
US Officials		
Tim Hall	US Diplomat, Economics Section, US Embassy in Brasilia	11 Dec 07

* Pre-Dissertation Interview

Institutions Visited	Location
Cristalia	São Paulo
Far-Manguinhos	Rio de Janeiro
Funed	Belo Horizonte, Minas Gerais
Furp	São Paulo
Hospital Emilio Ribas	São Paulo
Lafepe	Recife, Pernambuco
Ministry of Health	Brasilia
National AIDS Program	Brasilia
Nortec	Rio de Janeiro

Conferences Attended	Location	Date
1º ENI-FarMed - Encontro Nacional de Inovação em Fármacos e Medicamentos	São Paulo	21 Nov 07
Seminário sobre o Complexo Econômico-Industrial da Saúde	Rio de Janeiro	19-20 May 08
Seminário International Patentes, Inovação e Desenvolvimento	Rio de Janeiro	19-20 Jun 08
VII Congresso da SBDST e III Congresso Brasileiro de Aids	Goiania	7-10 Sep 08
Seminário Ano da França no Brasil - O Acesso aos Anti-Retrovirais nos Países do Sul: 20 anos após a introdução da Terapia Anti-Retroviral	Rio de Janeiro	11-12 May 09

APPENDIX THREE: PATENT SITUATION OF ARVS IN THE THERAPEUTIC CONSENSUS AND REGISTERED PRODUCERS IN BRAZIL

Active Principal (Market Name / Company)	Patent at INPI in Brazil	Depositor	Patent Situation in Brazil	ANVISA Patent Pre-Approval	Distri-buted by AIDS Program (year)	Public Pro-duction Started (year)	Public Labs with ANVISA Registration	Private Labs with ANVISA Registration
Nucleoside/Nucleotide Reverse Transcriptase Inhibitor (NRTI)								
Zidovudine-AZT (Retrovir / Glaxo Smith Kline)	Not Deposited	-	Not Protected	-	YES (1991)	1994	FM, Funed, Furp, LFM, Iquego, Lafepe, Lifal	GSK, Cellofarm, União Química, Prodotti, Blausiegel, Cristalia, Teuto, Eurofarma, Medapi, Ranbaxy
Didanosine-DDL (Videx / Bristol Meyers Squibb)	Not Deposited	-	Not Protected	-	YES (1993)	1998	FM, Iquego, IVB, Furp Lafepe, LFM, Lifal, Laqfa	Teuto, União Química, Ranbaxy, Serono, Solvay, Cristalia, Neoquimica, Cellofarm, Eurofarma, UCI, Medapi, Blausiegel, De Mayo, Bergamo, BMS, Prodotti, Germed
Didanosine enteric coated-DDL (Videx EC / Bristol Meyers Squibb)	PI9815861-9 PI9815948-8	Bristol Meyers Squibb Bristol Meyers Squibb	Granted (2003) Pending	Granted (2002) ?	YES (2004)	n/a	-	BMS
Zalcitabine-DDC (Hivid / Hoffman-La Roche)	Not Deposited	- -	Not Protected	- -	YES (1997) Removed (2000)	1998 Discontinued	Iquego, Lafepe, FM	Teuto, Prodotti
Stavudine-D4T (Zerit / Bristol Meyers Squibb)	Not Deposited	-	Not Protected	-	YES (1997)	1998	FM, Furp, IVB, Laqfa, Iquego	União Química, Aurobindo, Ranbaxy, BMS, Eurofarma, Cellofarm, Cristalia
Lamivudine-3TC (Epivir / Glaxo Smith Kline)	Not Deposited Not Deposited PI9808060	- - Wellcome	Not Protected Not Protected Pending	- - Granted	YES (1999)	1998	Lafepe, Furp, Iquego, IVB, Funed, FM, Laqfa	GSK, Medapi, Prodotti, Cristalia, Eurofarma Ranbaxy, Cellofarm,

		Foundation		(2008)				Blausiegal
Abacavir-ABC (Ziagen / Glaxo Smith Kline)**	PI1100288	Wellcome Foundation	Granted (1998)	?	YES (2001)	n/a	-	GSK
	PI9809126	Glaxo Group	Pending	?				
Tenofovir-TDF (Viread / Gilead Sciences)	PI9811045	Gilead Sciences	Denied (2008)	Priority Exam	YES (2003)	n/a***	FM, Funed***	United Medical
Non-nucleoside Reverse Transcriptase Inhibitor (NNRTI)								
Nevirapine-NVP (Viramune / Boehringer Ingelheim)	Not Deposited	-	Not Protected	-	YES (2001)	2000	FM, Iquego, Lifal, Funed	Cellofarm, Medapi, Boehringer Ingelheim, Ranbaxy Eurofarma, Aurobindo, Cristalia
Delavirdine-DLV (Rescriptor / Agouron)	Not Deposited	-	Not Protected	-	YES (1998)	1998	-	-
	PI9910481	Pharmacia & Upjohn	Pending	?	Removed (2000)	Discontinued		
Efavirenz-EFZ (Sustiva / Bristol Meyers Squibb licensed to MSD in Brazil)**	PI9908810	Du Pont Pharmaceuticals	*Compulsory License*	-	YES (1998)	2009	Lafepe, FM	Cristália, Cellofarm, MSD
Protease Inhibitors (PI)								
Atazanavir-ATV (Reyatez / Bristol Meyers Squibb)	PI9701877	Novartis	Granted (2004)	Granted (2004)	YES (2004)	n/a	-	BMS
	PI9814736	Bristol Meyers Squibb	Pending	?				
Saquinavir Mesylate-SQV (Invirase / Roche)	PI9006264	Roche	Denied (1999)	-	YES (1996)	n/a	-	Merck S/A, União Química,
Saquinavir-SQV (Fortovase / Hoffman-La Roche)	PI9610842	Roche	Granted (2005)	Granted (2004)	NO	n/a	-	Roche, Cristalia
	PI9915444	Roche	Pending	?				
Ritonavir-RTV (Norvir / Abbott)	PI1100661	Abbott	Pending	?	YES (1996)	n/a	Lafepe	Abbott, Cristalia, Merck S/A, Neo Quimica
	PI9912010	Abbott	Pending	Returned to INPI (2006)				
Indinavir-IDV (Crixivan / Merck)	PI9406576	Merck	Denied (2003)	?	YES (1997)	2000	FM, Furp, Iquego, Lafepe, Lifal	MSD, Cristalia, Eurofarma, Medapi, Ranbaxy, Cellofarm, Germed
Nelfinavir-NFV (Viracept / Agouron licensed to	PI1100166	Agouron	Granted (1999)	?	YES (1997)	n/a	Iquego	Roche, Medapi, Cristalia, Cellofarm

Roche in Brazil)**								
Amprenavir-APV (Agenerase / Glaxo Smith Kline)**	PI1100824	Vertex	Granted (1999)	?	YES (2001)	n/a	-	GSK
Fosamprenavir-FPV (Telzir/Glaxo Smith Kline)	?	?	?	?	YES (2007)	n/a	-	GSK
Darunavir-DRV (Previzta / Tibotec)	PI0416187	University of Tulane	Pending	?	YES (2007)	n/a	-	Janssen
Entry Inhibitor (EI)								
Enfuvirtide-T-20 (Fuzeon / Hoffman-La Roche)	PI0314651	Trimeris	Pending	?	YES (2005)	n/a	-	Roche
	PI0314707	Trimeris	Pending	?				
Integrase Inhibitor (II)								
Raltegravir-RAL (Isentress/Merck)	PI0508495	Merck	Pending	?	YES (2008)	n/a	-	Merck
Fixed Dose Combinations								
Lamivudine + Zidovudine- (Combivir / Glaxo Smith Kline)	PI9712614	Glaxo Group	Denied (2006)	Denied (2006)	YES (1999)	1999	FM, Lafepe	União Química
Abacavir + Lamivudine + Zidovudine (Trizivir / Glaxo Smith Kline)	PI9607851	Wellcome Foundation	Granted (2008)	Granted (2008)	NO	n/a	-	-
Lopinavir + Ritonavir-LPV/r (Kaletra / Abbott) **	PI1100397	Abbott	Granted (2000)	?	YES (2001)	n/a	-	Abbott

Other ARVs not included in the therapeutic consensus: Tipranavir- TPV (Aptivus/Boehringer-Ingelheim), Emtricitabine- FTC (Emtriva/Gilead), Maraviroc- (Celsentri/Pfizer), Abacavir + Lamivudine + Zidovudine (Trizivir / GSK) and Emtricitabine + Tenofovir + Efavirenz- (Atripla/ Gilead and BMS).

Note: *Patents refer to chemical entities, processes and formulations. Companies use different strategies for patenting. Therefore some active principals have more than one patent with different expiration dates. **ARVs patented through the pipeline. ***FM and Funed chosen to develop and produce the ARV.

Source: Hasenclever et al (2004) plus author, using websites of National Institute on Intellectual Property (Instituto Nacional de Propriedade Intelectual—INPI), National AIDS Program, and ANVISA.

APPENDIX FOUR: TRIPS FLEXIBILITIES AND RELATED BRAZILIAN INTELLECTUAL PROPERTY LEGISLATION

TRIPS FLEXIBILITY	BRAZILIAN IP LEGISLATION
(1) **Transition period**: The deadline that member countries have for making domestic laws compliant with TRIPS varies depending on their level of development. High-income countries had until 1996 to change their laws; middle-income countries, including Brazil and India, 2005; and least developed countries have until 2016. (Art. 65 and 66)	Brazil approved Industrial Property Law #9.279 in 1996 and implemented it the following year, several years before the 2005 deadline
(2) **Experimental exception**: The patent will not prohibit the experimental use of an invention by third parties for scientific purposes.	Included in Industrial Property Law #9.279
(3) **"Bolar"/Early working exception**: Third parties may carry out all the necessary tests and procedures required for the registration of generic versions before their patent expires. (Art. 30)	Law # 10.196 passed in 2001 amends articles 43 in Law #9.279 to provide for this exception
(4) **Parallel imports or Exhaustion of Rights**: Without the consent of the patent holder on the domestic market, a product may be resold or imported from another country where the patent holder has authorized it to be placed on the market. (Art. 6)	Decree # 4.830 of 2003 amends Decree #3.201 to allow parallel importing of patented products when a compulsory license is issued
(5) **Prior use**: If a person uses an invention before a patent is filed for the product, s/he may be granted the right to continue using the invention despite the granting of the patent. (Art. 30)	Included in Industrial Property Law #9.279
(6) **Compulsory License**: The main legal instrument for correcting abuses by patent holders is the compulsory license (CL), which allows for the exploitation of a patent by third-parties without the consent of the patent holder. Use of a CL is proscribed in six instances: a. refusal to deal; b. cases of emergency or extreme urgency; c. remedy anti-competitive practices; d. failure to obtain voluntary license under reasonable terms; e. public non-commercial use; and f. dependent patents for innovations requiring patented inputs. Before issuing a compulsory license, a government must first attempt to reach a negotiated settlement with the patent holder, who, in the case of the CL, still has the right to receive royalties. There are two exceptions. First, negotiating a voluntary license is not required in cases of a national emergency and public, non-commercial use. Second, royalty payments may not be necessary when a CL is issued to correct anti-competitive practices.	Industrial Property Law #9.279 states a CL can be issued for the following reasons: failure to exploit patent; public interest; national emergency; remedy for anti-competitive practices; and failure to produce locally and dependent patents Decree # 3.201 of 1999 specifies the criteria for issuing a compulsory licensing in cases of national emergency and public interest Decree # 4.830 of 2003 amends Decree #3.201 to allow parallel importing of patented products when a compulsory license is issued
(7) **Prior Consent and Pre-grant Opposition:** Countries can determine the appropriate method of implementing the provisions of TRIPS within their legal system; consequently, domestic	Law # 10.196 of 2001 amends article 229 in Law #9.279 stating that National

legislation may allow other government agencies or members of society to participate in patent application process (Art. 1.1).	Health Surveillance Agency (ANVISA) must give prior consent before patents are granted on all pharmaceutical products and processes. (Prior consent was first established by Presidential Directive in 1999).
(8) **Pipeline versus Mailbox:** A pipeline patent is a form of retroactive protection for drugs already patented in other countries but not marketed at the time TRIPS comes into force. Otherwise, a mailbox system allows applications for patents for pharmaceutical product inventions to be filed but not examined until the end of the transition period (Art. 70.8).	Industrial Property Law #9.279 of 1996 allows for pipeline patents.
(9) **Data Exclusivity**: Grants protection for undisclosed data drug firms provide to regulatory officials in order to obtain marketing approval. Extending the timeframe for protecting undisclosed data, a TRIPS-plus measure, restricts competition from generic drugs markers that could lower prices (Art. 31).	Law # 10.603 of 2002 provides protection to up to 10 years for drugs that include new chemical entities and 5 years for all other drug for undisclosed test data drug firms provide to ANVISA.

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